

Audit Report

Report No: 0713308726

Version 1



Product Service

Order Number	0713308726
Audit Mode	On-Site
Type of Audit	<input type="checkbox"/> Stage 1 <input type="checkbox"/> Stage 2 <input type="checkbox"/> Stage 1 + Stage 2 <input checked="" type="checkbox"/> Re-Certification <input type="checkbox"/> 1st Surveillance <input type="checkbox"/> 2nd Surveillance
Audit criteria	<input checked="" type="checkbox"/> (DIN) EN ISO 13485:2021 <input checked="" type="checkbox"/> EN ISO 13485:2016+A11:2021 <input type="checkbox"/> ISO 13485:2016 <input checked="" type="checkbox"/> ISO 9001:2015 <input checked="" type="checkbox"/> Defined processes and documentation of the auditee's Quality Management System <input checked="" type="checkbox"/> Taiwan GMP <input type="checkbox"/> Other: <input checked="" type="checkbox"/> European Directives including the additional requirements of MDR Article 120 (3) after May 26 th 2021 and IVDR Article 110 (3) after May 26 th 2022: <input checked="" type="checkbox"/> Council Directives 93/42/EEC (MDD) – annex II (w/o 4) <input type="checkbox"/> Council Directives 93/42/EEC (MDD) – annex V <input checked="" type="checkbox"/> European Regulations: <input checked="" type="checkbox"/> Medical Device Regulation (EU) 2017/745 – annex IX Chapters I and III <input checked="" type="checkbox"/> MDSAP with additional country-specific requirements: <input checked="" type="checkbox"/> Australia (TGA) <input checked="" type="checkbox"/> Brazil (ANVISA) <input checked="" type="checkbox"/> Canada (HC) <input checked="" type="checkbox"/> Japan (MHLW/PMDA) <input checked="" type="checkbox"/> United States (FDA)
Audit period (on site)	2023-09-18 - 2023-09-22
Auditee (s) / Location(s)	1) Drägerwerk AG & Co. KGaA, Moislinger Allee 53-55, 23542 Lübeck, GERMANY (10578) 2) Drägerwerk AG & Co. KGaA, Revalstrasse 1, 23560 Lübeck, GERMANY (90464)
Audit Responsible	Ulf Hagedorn
Lead Auditor / Auditor	Martin Szepannek / George Pavlov, Melanie Gaßen, Gabriele Mousset (under routine-monitoring ISO 9001 by M. Szepannek), Honorata Donnermaier
Expert / Trainee	Somesh Rasal (deputy Expert for Jan Küffner) - Cybersecurity
Auditor/ Expert Covering Code	George Pavlov (MDT 2002, MDT 2010, MDT 2011, MDT 2012, EAC 14, EAC 19, EAC 33, MDA 0203, MDA 0307, MDA 0315, MD 1101.1, MD 1301, MD 1302, MD 1402_1, MDS 1005_2, MDS 1009, MDS 7006_2) Gabriele Mousset (EAC 19, MDT 2010, MDT 2011, MDT 2012, MDA 0307, MDA 0315, MDA 0312_1, MD 1101.1, MD 1102, MD 1111, MD 1301) Honorata Donnermaier (MDT 2001, MDT 2003, MDN 1201) Martin Szepannek (EAC 19, MDT 2010, MDT 2011, MDA 0203, MDA 0303.1, MD 1301, MDA 0307, MDA 0315, MDA 0316, MD 1302) Melanie Gaßen (MDT 2002, MDN 1201, MDN 1214, MD 0101.1)
Auditor Reg. No. (Mainland China only)	n/a
Translator / Observer and their organization	n/a
Audit Language	German / English
Client / Company and Company Number	10578 Drägerwerk GmbH & Co KGaA
Client Management Representative	Stefanie Hirsch (Head of Quality & Regulatory Affairs)
TUV SUD Contact	Maximilian Sanno, MHS-AP5
Proposed next regular Audit - Date / Type of audit	September 16, 2024

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1 Information about the company, scope, audited facilities, general

The application's appendix A/B/C for the applicable certificate contains comprehensive information about the company, including current certification scope, processes, relevant facilities, critical suppliers, contact person(s), products, management system etc. The application's appendix A/B/C is released together with this audit report.

2 Data concerning Audit

2.1 Audit scope, objectives, and criteria

The audit plan contains detailed information about the audit. The specific audit scope as documented in the audit plan defines locations / organizational units, activities, and processes with reference to standard clauses covered during this audit as well as to related audit duration (see section 2.2).

The objective of this audit is to verify the conformity and effectiveness of the manufacturer's quality management system (or parts of it) with applicable requirements (statutory, regulatory, and contractual requirements, etc.) as specified on page 1, to ensure reasonable expectation it can achieve its specified objectives.

Representative areas of the client/company organization were audited on a sample basis to achieve an overview of the Quality Management System's effectiveness. A management system certification Audit (initial, surveillance or recertification Audit) is not a legal compliance Audit (see ISO/IEC 17021-1:2015, 9.2.1.2 b).

2.2 Audit location and time

The following site(s)/ facility(ies) were visited during this Audit:

#	Client Number	Site/ Facility	Audit duration (on-site man-days)
1	10578	Drägerwerk AG & Co. KGaA, Moislinger Allee 53-55, 23542 Lübeck	12,6
2	90464	Drägerwerk AG & Co. KGaA, Revalstrasse 1, 23560 Lübeck	7,0

See latest version of audit plan for Audit Duration.

2.3 Audit Team

See page 1 for Audit Team composition as well as included Experts (if applicable). The audit team is authorized for the audit criteria mentioned on page 1 of this report.

Until May 25th 2021 TÜV SÜD Product Service GmbH was the Notified Body for conformity assessment according to the directives 93/42/EEC (MDD) and 90/385/EEC (AIMDD) listed on NANDO.

On the respective Date of Application of the regulations and according to MDR Art. 120(3) (May 26th 2021) TÜV SÜD Product Service GmbH is responsible for the appropriate surveillance of all applicable requirements relating to the devices it has certified under MDD.

TÜV SÜD America Inc. is the Auditing Organization for Medical Device Single Audit Program (MDSAP).

TÜV SÜD Japan is the Registered Certification Body under Japanese Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (PMD Act).

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2.4 Audit preparation

Prior to the Audit the following documentation was reviewed and used as an input for Audit planning.

- ☒ Updated applicable application(s)' appendix A/B/C including site/facility data, codes and certificate data relevant for the Audit project (see attachment for current version)
- ☒ Audit program and calculated audit duration taking into consideration reported changes in the organization, quality management system or products (see section 3.2)
- ☒ Quality management system documentation information
- ☒ Any certified client's statements with respect to its operations for review of proper promotional use of certifications (certificates and certification marks). This includes checking e.g., promotional material and website content and any referenced links and attachments. Use of certification mark and references in documents, product labelling and websites must not be misleading.
- ☒ Post market surveillance data collected from the manufacturer or in public accessible data bases (see section 3.1)
 - Information from the vigilance reporting system
 - Recalls performed
 - Field safety corrective action(s)
 - Field safety notices
- ☒ Post market surveillance data collected for product code / specific characteristics from applicable test program (PPP, PPP MDR, PPP IVDR) (see section 3.1)
- ☒ Audit report from the previous audits (regular, unannounced and special) including findings and customer responses (if applicable, see section 2.8)
- ☒ Evaluation results of changes to quality management system or device-range covered by the certificate(s) including change notification approval(s) (if applicable, see section 3.2)
- ☒ Relevant information filed against the client at any TÜV SÜD certification body involved (if applicable, see section 2.9)
- ☐ Results of technical documentation assessments to be followed up during the next audit (if applicable, see section 2.9)
- ☒ Audit release information issued by the certification body(ies) (if applicable, see section 2.9)
- ☒ The CBW facility report(s) has / have been checked for any "action items" derived from various sources including internal MHS-CRT information about vigilance cases from the manufacturer or competent authorities (if applicable). Applicable "action items" (if any) are addressed in section 2.9 of this report.
- ☒ Re-Certification Audit: Audit results from the last three years were considered for Audit planning of this Audit

3-Year History	Reports Number(s)	Major NC	Minor NC	MDSAP Grades	Comments / Systemics
Recertification (2020)	0713193628	0	4	3,4,3,3	none
Surveillance 1 (2021)	0713225401	1	4	3,1,3,3,3	none
Surveillance 2 (2022)	0713270541	0	5	1,3,3,3,3	none
UAA (2022)	0713277581	0	0	--	none
Notes	---	---	---	---	---

2.5 Audit Trails

Description of activities covered during the Audit, key element summary for each audited subsystem.

2.5.1 Management and Quality Management System

Subsystem	Management - Quality Management System
Audit trail records of	Martin Szepannek / George Pavlov / Gabriele Mousset / Honorata Donnermair
Area(s) visited (location, e.g., site visited)	Location # 10578 (all Tasks) Location # 90464 (Task 9/11) For more details related to audit location and time refer to chapter 2.2 of this report.
Audit criteria according to audit plan	<p>"Management: QMS Planning, Implementation, Changes and Quality Manual (MDSAP Chapter 1, Task 1, Site: 10578); (DIN)(EN) ISO 13485 - 4.1.1, 4.1.2, 4.1.3, 4.2.2, 4.1.4, 5.4.2 + (DIN)(EN) ISO 9001 - 4.3, 4.4, 6.1, 6.3, 7.5.1, 8.4 + MDSAP - Australia - TG(MD)R Sch3 P1 1.4(4) + MDSAP - Brazil - RDC ANVISA 16/2013: 2.1, 5.6 + MDSAP - Japan - MHLW MO169: 5-1, 5-2, 5-3, 5-4, 7, 14; [Old3: 5, 7, 14] + MDSAP - USA - 21 CFR 820.20 + MDR - Article 10.8 ¶1, 10.9 ¶1 S2, 10.9 ¶3 (a, e); Annex IX 2.1(2), 2.2 ¶2 (c1, c3); Annex XI 6.4 + MDD - Annex II (3.1,3.2)"</p> <p>"Management: Management Representative (MDSAP Chapter 1, Task 2, Site: 10578); (DIN)(EN) ISO 13485 - 5.5.2 + (DIN)(EN) ISO 9001 - 5.3 + MDSAP - Australia - TG(MD)R Sch3 P1 1.4(5)(b)(ii) + MDSAP - Brazil - RDC ANVISA 16/2013: 2.2.5 + MDSAP - Japan - MHLW MO169: 16 + MDSAP - USA - 21 CFR 820.20(b) + MDR - Article 15 + MDD - Annex II (3.2)"</p> <p>"Management: Quality Policy and Quality Objectives (MDSAP Chapter 1, Task 3, Site: 10578); (DIN)(EN) ISO 13485 - 5.3, 5.4.1 + (DIN)(EN) ISO 9001 - 5.2, 6.2 + MDSAP - Australia - TG(MD)R Sch3 P1 1.4(5)(a) + MDSAP - Brazil - RDC ANVISA 16/2013: 2.2.1 + MDSAP - Japan - MHLW MO169: 12, 13 + MDSAP - USA - 21CFR 820.20(a) + MDR - Annex IX 2.2.¶2 (a); Annex XI 6.2 ¶2 + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>"Management: Organizational Structure, Responsibility, Authority, Resources (MDSAP Chapter 1, Task 4, Site: 10578); (DIN)(EN) ISO 13485 - 5.1, 5.5.1, 5.5.2, 6.1, 6.2 + (DIN)(EN) ISO 9001 - 5.1, 5.3, 7.1.1, 7.1.2, 7.2, 7.3 + MDSAP - Australia - TG(MD)R Sch3 P1 1.4(5)(b) + MDSAP - Brazil - RDC ANVISA 16/2013: 2.2.2, 2.2.3, 2.2.4, 2.3 + MDSAP - Japan - MHLW MO169: 10, 15, 16, 21, 22, 23 + MDSAP - USA - 21 CFR 820.20(b), 820.25 + MDR - Annex IX 2.1(6)¶2, 2.2 ¶2 (a, b1); Annex XI 4 & 6.2 ¶2; Article 10(16) + MDD - Annex II (3.1, 3.2), Annex V (3.1, 3.2), Annex VI (3.1)"</p> <p>"Management: Extent Of Outsourcing (MDSAP Chapter 1, Task 5, Site: 10578); (DIN)(EN) ISO 13485 - 4.1.5, 4.2.1 + (DIN)(EN) ISO 9001 - 4.4, 8.4, 7.5.1 + MDSAP - Australia - As required by MDSAP AU P0002 + MDSAP - Brazil - RDC ANVISA 16/2013: 2.5 + MDSAP - Japan - MHLW MO169: 5-5, 6; [Old: 5, 6] + MDSAP - USA - 21 CFR 820.50 + MDR - Article 10.9 ¶3 (d); Annex IX 2.2 ¶2 (a, b3); Annex XI 6.2 ¶2, 12 ¶1; Article 10 (15) + MDD - Annex II (3.2 (b, d, e)), Annex V (3.2(b, c, d), Annex VI (3.2), [EK-MED 3.09B16]"</p> <p>"Management: Personnel Competency and Training (MDSAP Chapter 1, Task 6, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 6.2 + (DIN)(EN) ISO 9001 - 7.2, 7.3, 7.5.1 + MDSAP - Brazil - RDC ANVISA 16/2013: 2.2.3, 2.2.4, 2.3 + MDSAP - Japan - MHLW MO169: 6, 22, 23 + MDSAP - USA - 21 CFR 820.20(b)(2), 820.25 + MDR - Annex IX 2.1 ¶1, 2.2 ¶2 (a), Article 15, [MPDG §83] + MDD - Annex II (3.1, 3.2), Annex V (3.1, 3.2), Annex VI (3.1)"</p> <p>"Management: Risk Management Planning and Review (MDSAP Chapter 1, Task 7, Site: 10578); (DIN)(EN) ISO 13485 - 4.1.2 (b), 7.1 + (DIN)(EN) ISO 9001 - 4.4, 8.1, 8.4 + MDSAP - Australia - TG(MD)R Sch1 P1 2 + MDSAP - Brazil - RDC ANVISA 16/2013: 2.4 + MDSAP - Japan - MO169: 5-2.1.2, 26; [Old: 26] + MDSAP - USA - 21 CFR 820.30(g) + MDR - Article 10.9 ¶3 (e); Annex IX 2.2 ¶2 (c3); Annex I (2.3,4,5,8) & II (5) + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>"Management: Document and Record Controls (MDSAP Chapter 1, Task 8, Site: 10578); (DIN)(EN) ISO 13485 - 4.1.4, 4.2.1, 4.2.4, 4.2.5 + (DIN)(EN) ISO 9001 - 4.4, 7.5.1, 7.5.2, 7.5.3, 8.4 + MDSAP - Australia - TG(MD)R Sch3 P1 1.4(4), 1.9; Reg 5.10 + MDSAP - Brazil - RDC ANVISA 16/2013: 3.1 + MDSAP - Japan - MO169: 5-4, 6, 8, 9, 67, 68; [Old: 5, 6, 8, 9] + MDSAP - USA - 21 CFR 820.40, 820.180 + MDR - Article 10.8 ¶1, 10.9 ¶1 S2; Annex IX 2.2 ¶2 (a, c); Annex XI 12 ¶1; Article 10, 11, 12, 22, 27, 29, 31, 51, 52, [MDCG 2019-16, 2021-19], [MPDG § 5]] + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.1, 3.2) [EK-MED 3.09 B20]"</p> <p>"Management: Management Reviews (MDSAP Chapter 1, Task 9, Site: 10578); (DIN)(EN) ISO 13485 - 5.6 + (DIN)(EN) ISO 9001 - 9.3 + MDSAP - Australia - TG(MD)R Sch3 P1 1.4(5)(b)(iii)(f) + MDSAP - Brazil - RDC ANVISA 16/2013: 2.2.6 + MDSAP - Japan - MO169: 18, 19, 20 + MDSAP - USA - 21 CFR820.20(c) + MDR - Article 10.8 ¶1 S2; Annex IX 2.2 ¶2 (c8) + MDD - Annex II (3.1), Annex V (3.1), Annex VI (3.1)"</p> <p>"Management: Distribution of Devices with Appropriate Marketing Authorization (MDSAP Chapter 1, Task 10, Site: 10578); (DIN)(EN) ISO 13485 - 4.1.1, 4.2.1, 5.2, 7.2.1, 7.2.3 + (DIN)(EN) ISO 9001 - 4.4, 5.2.1, 7.5.1, 8.2.1, 8.2.2, 8.4 + MDR - Article 10.9 ¶3 (a); Annex IX 2.2 ¶2 (c1), Article 19, Annex IV, Annex IX ch III.6, Annex XI 2, 6 + MDD - Annex II (3.2)"</p> <p>"Management: Top Management Commitment to Quality (MDSAP Chapter 1, Task 11, Site: 10578); (DIN)(EN) ISO 13485 - 4.1.1, 4.1.4, 5.1, 5.5.3 + (DIN)(EN) ISO 9001 - 4.4, 5.1.1, 7.4, 8.4 + MDSAP - Brazil - RDC ANVISA 16/2013: 2.1, 2.2.1 + MDSAP - Japan - MO169: 5-1, 5-4, 10, 17; [Old: 5, 10, 17] + MDSAP - USA - 21 CFR 820.20(a), 820.5 + MDR - Article 10.9 ¶3 (c) + MDD - Annex II (2, 3.1)"</p>
Brief description of processes or activities evaluated to demonstrate what was audited related to the listed key QMS documents and records reviewed below considering inputs, outputs, and measures	<p>General Info (GM)</p> <p>>16.000 employees word wide 3,4 Mio EUR net sales Lübeck HQ (DWAG) (Moislinger Allee) , Revalstr. (production and logistics) Safety and Medical Business (Medical Business around 2/3 of annual revenue) Organised in therapeutical Busienss Units (BU Therapy, Patient Monitroing, Workplace Infrastructure, Hospital Consumables and Accessories, Global Services) Production Sites Worldwide DWAG = Drägerwerk AG 2240 Employees in Medical Business 895 in R+D 630 n Production 1530 in Moislinger allee 710 in Revalstraße (Production)</p> <p>Changes since last year: BU Therapie: EVITA some products in phase out New product M11.3 (CO² sensor) EVITA group Changes release 2.0 and prep 3.0 Qxylog 3000 Plus, SW change to v 1.10 Savina 300 new SW Version 5.02.01 Savina Color EoP June 2023 ATLAN family (A 300/A350), new SW features, v.2.0 (Cyber) and bugfixes, all MDSAP countries Perseus A500 CE mark MDR since 04/2023 Zeus IE, SW update 2.03, only Australian and Canada</p> <p>Dräger One PM: ICM (integrated Care Manager), SW14.0.0 New product: lung protective ventilation analytics, non medical SW SPV smart pilot view; v 3.03, currently TD review stage Core new product, Infinity to STC and back, SW 1.0 + Converter Service, currently TD review stage</p>

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	<p>MPW (mobile patient watch), v2.0, functional enhancements, IIB</p> <p><u>BU WPI:</u> Ambia ceiling supply, SW 2.2 Ponta, MDR since 2023, IIB Valia New Arm System (supplier Ondal), IFU changes, handle material change, MDR CE Mark class I</p> <p><u>BU HCA:</u> Delta P Flow Sensor (oxylog family), MDR Mai 2023 Self test lung, product enhancement, reprocessing optimized, November 2022 ; MDR class I HumidStar 2 Plus Luer-Lock, different sizes available, August 2023 IIa MDR Supplier location change Bood pressure cuffs, reusable and single change MD calss I, change January 2023 Vascumat Tube class I, new supplier and Dräger design change</p> <p><u>Organization /IT/processes:</u> BU Therapie restructured. BU Data business terminated (e.g. Dräger one to PM Clinical and central regulary affairs one BU Stepahn Kruse (BU Therapy) left the company. Dr Rainer Wobe (BU clinical affaires) left. Dr. Bettina Möbius new Head of central clinical and regulatory affairs IT Systems Change to S4 HANA Processes: continuous update</p> <p>*****</p> <p>ISO 9001: There is a process in place to continual improvement (see Management review) There is evidences for stringent customer focus / satisfaction (see section below, Device Marketing Authorization and Facility Registration / Customer Related Processes) There is a process in place for Changes and risks (see CAPA, and D&D changes) There is evidences for knowledge management (see Management review)</p> <p>See also extra section for ISO 9001</p> <p>*****</p> <p>Management Responsibility</p> <p>M1 - Quality Management System Planning (MSz) Confirmed that quality management system planning is performed to ensure that all required processes are identified, documented, implemented, monitored and maintained in order to conform to the applicable requirements and meet quality objectives. Verified that changes to the quality management system are managed to maintain the conformity of the quality management system and of the devices produced. Verified that a quality manual has been documented. Dräger keeps an Integrated Management Systems that applies to all Dräger Companies and integrates processes with different underlying Stakeholder requirements, i.e. regulatory, quality, environmental, health and Safety, and financial requirements. BIC (Business Information Center) is used as process management system. All process descriptions are included within that system (this exceeds regulatory required processes). Furthermore the process flow charts are displayed, responsibilities, inputs, outputs, templates etc. Corporate QRA is responsible for approval of Global Standards and Draägerwerk Ag & Dräger safety AG. Local adopted standards are approved by Global process Owners in alignment with Corporate QRA, if local Quality Manager has specific local needs. Localisation rules are implemented, usually they allow for translations, minor changes to process step descriptions, forms, tools, responsibilities, applications, references to internal and external documents. See DEALL PQ 3130.</p> <p>Interested Parties are: - Authorities and Certification Bodies - Business partners - Customers - Dräger family - Employees - Financial Stakeholders - Legislation - Society Their main requirements to the organisation are documented within Quality manual 4.1 Corporate Strategy.</p> <p><u>M2 - Management representative, awareness (GM) 5.5.2</u> <u>Regulatory requirements</u> MDR: Article 15; Annex IX 2.1 & 2.2 (2a, b1); Annex XI 4 & 6.2(2); Article 10(16) MDD: Annex II (3.1, 3.2), Annex V (3.2), Annex VI (3.2) (e.g. Declaration of conformity/ system etc)</p> <p>Management Representative's appointment and responsibilities are documented in organization charts and Job descriptions.</p>

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Subsystem	Management - Quality Management System
	<p>Job description Stefanie Hirsch (medical devision/corporate Q&RA Leader) with tasks of management representative and PRRC were reviewed. Role description includes several details as e.g. RA and clinical and TD declaration of conformity. SH is also appointed as authorized representative for Dräger DMSI (USA- Monitoring Systems). PRRC role is divided into several responsibilities (TD and DoC's responsibility Stefanie Hirsch) Frau Hilmer (PRRC PMS) Frau Hering (PRRC clinical aspects) and others. All PRRC responsibilities are documented in Liste ausgewählter Beauftragter im IMS, which have been audited.</p> <p><u>M3 - Quality policy, objectives (GM) 5.3, 5.4.1;5.1; 4.2.1(a)</u> Quality policy and objectives have been set at relevant functions and levels within the organization. The quality objectives are measurable and consistent with the quality policy, the overview of objectives (QM initiatives) in MR as well as an example of follow up (RIM/ARAS) migration have been audited. Quality objectives are deduced from the strategic quality aspects: e.g. renewal of product-portfolio/system- infrastructure/system applications/ efficacy/organization mindset/external triggers Quality objectives are followed up by action plans that define sub targets, responsible person(s), due dates and resources needed. Overview regarding project-status and needed actions will be given e.g. by monthly "Führungskreis Meetings": QAA Steering Meeting medical/QAA Steering meeting corporate.Additionally, weekly QAA standup meeting will be performed for tracking of relevant QM topics and actions.</p> <p><u>M4 - Org. structure, responsibilities (GM) 5.5.1; 6.1 ;5.1; 6.2 (Moisler- and Revalstr.)</u> The manufacturer's organizational structure and related documents have been reviewed. Organizational structure have been presented during audit in introduction presentation with links to concrete org. Charts (related Q documents). Responsibilities and authorizations are described by functional descriptions. Disciplinary and reporting lines are outlined in the organizational chart. PRRC and medical representative is announced (see also M3). For all MDD medical products the product owners are responsible. MDR role PRRC is divided into subset responsibilities with different persons in charge (see M3). The critical roles in respect to the QMS are listed and dedicated in document "Liste ausgewählter Beauftragter im IMS"</p> <p><u>M5 - Extent of Outsourcing (HD)</u> According to the QMH the outsourced processes are monitored and managed according to internal procedures. A list of outsourced processes in maintained and was demonstrated during the audit. The outsourced process includes examples such as: - Archiving of documents & records - Design & Development - Human Resources, training organization & record Administration - Installation, repair & maintenance (to Drager Sales & Service entities) - IT-Services - Logistic services incl. final inspection & test - Sterilization - Supply of finished medical devices</p> <p>List of approved suppliers was demonstrated. Spot check made based on sampling – The supplier of 2K seals (contact with breathing gas) supplier Trellabo Sealing CS 11649 and supplier AB Ulax CS 145240 (supplier of medical device Humidstar 2+LL) - were found in the list. The suppliers based on the classification and criticality underlay different monitoring measurements such as annual delivery and quality evaluation (DQPE), audits etc. The QSV, audit reports and DQPE for both sampled suppliers were reviewed during the audit.</p> <p>Additional country-specific requirements: Australia: The Drager Australia Pty is identified as AU Sponsor. The Distribution Agreement with Draeger Australia PTY was demonstrated. Canada CANADIAN Regulatory role is fulfilled by the Regulatory Affairs Central in Lubeck, The Canadian distributor is not performing the role. The Canadian Distribution Agreement is available and demonstrated as email.</p> <p><u>M6 - Competencies for personnel (GM) 6.2</u> The team manager determines the required trainings for each employee (role specifics), together with the qualifications which are communicated to HR and evaluated once a year. Basic requirements are predefined for types of roles and entities (e.g. leader, or D&D) The team leaders are responsible to communicate the requirements for new employees. There are general trainings that all employees should perform (e.g.: data security, work safety, among others). The responsibility of the performance of the trainings is taken by the corresponding management. Once the requirements have been identified, there will be training measures set. Depending on characteristics of needed qualifications trainings will be identified covering required competences. The trainings performed are documented in training records. Templates are used (e.g. Teilnehmerliste).Trainings could be online or onsite trainings. Effectiveness checks of trainings can be defined individually for all trainings and e.g. documented on "Teilnehmerliste" or other supplemental documents if needed. Generally, the effectiveness checks will be performed during each training. The team leader determines whether additional effectiveness checks of the trainings should be done, based on the responsibilities of the employee (the latest Q-check). A yearly effectiveness check will be performed by team leaders for every employee and documented on Q-Check template. Additionally, an individual appraisal will be performed for each employee which can be denied by employee but is mandatory to provide by teamleader. Generally the appraisals will not be documented (requirement defined by "Beriebsrat"). In case of needed actions these will be documented in action-plans for the respective employee.</p>

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	<p>Overview of trainings per role or employee can be seen in "Trainingsportal" (TCM)</p> <p>Q-Check document: is the document to control which kind of trainings have been performed individually and shows the status of those trainings. All the trainings which are defined in the Q-Check are mandatory.</p> <p>The Q-Check can be released only when all trainings are completed or planned.</p> <p>The general documentation of the trainings is the participants list, there are also other records e.g.: prove of competence, self-study and the corresponding documentation, external certificates will be also accepted as training records.</p> <p>The Q-Check incl. update of documentation is performed once a year. In case the required trainings are not fulfilled or in case of lack of competency, it is responsibility of the corresponding managers to implement measures. The training records are stored paperbased and Q Checks additionally on a the central system TCM.</p> <p>Onboarding training is the same as described above. The defined trainings (basic and individual once) should be done during the first 3 months (latest after one year). The temleader is responsible to check whether all mandatory trainings have been performed before giving any quality relevant tasks to the employee.</p> <p>Brazil :</p> <p>Confirm that the manufacturer ensures that any consultant who gives advice regarding design, purchasing, manufacturing, packaging, labeling, storage, installation, or servicing of medical devices has proper qualification to performsuch tasks. Those consultants shall be contracted as a formal service supplier, according to purchasing controls defined by the manufacturer [RDC ANVISA 16/2013: 2.3.3].</p> <p>External consultants will be addressed in Purchasing session Mr Pavlov.</p> <p>The training process will be also followed for external employees (especially regarding definition of needed trainings and Q-Check`s). For sub-contractors, the qualifications should be put in respective contracts.</p> <p>There is an online training - platform in place (TCM) used for internal and external personnel, which can be configured to show the requirements of the roles, the qualifications are defined within packages (e.g. leader; rsik managemenet etc.). The training status is identified in colour code (red and green).</p> <p>The tool allows the users to select the trainings and perform them, either online or onsite.</p> <p>The Medical Consultants should have several trainings related to their responsibilities; the respective managers determine which qualifications are needed according to the products and roles they are assessing.</p> <p>A council determines the required qualifications for the different roles. This includes participants from the legal, HR, Data security, compliance, operations, quality, academy departments.</p> <p>A Trainer is a person, which is qualified to perform training measures, he/she will be selected by the training organization and Dräger.</p> <p>Trainings will be performed by experienced employees.</p> <p><u>M7 - Risk Management Planning and Review (HD)</u></p> <p>The organization has established risk management throughout the quality management system, the link to the other processes such as clinical evaluation, change management, R&D, PMS is evident. The main description of the risk management process is defined in Risk Policy and acceptance criteria. The process defines 12 steps (plan RM process, plan change specific RM, identify hazards, support CE process, evaluate identified risks, review RM process etc)</p> <p>The acceptance criteria (insignificant, considerable and substantial) are available in Attachment A06 to the risk policy. In section 3 overall residual risk is considered. Overall risk management is reviewed on a regular base. The detailed risk management process related to design is performed during design and development process.</p> <p>The link to management review is established. Overview of risk management is a part of the annual management review (Product Risk Management incl. product usability). In the most recent management review the following KPIs are defined: occurrence rate of harm, PSUR/ PMSR performed and required Risk Reducing Measures, status – withing acceptance thresholds 33/0.</p> <p>The risk management system is fully effective. However, the tight resource situation in one area (BU Therapy) needs to be reviewed.</p> <p>The annual risk reports for flow sensor (MP 20092 and MP 20093) were presented.</p> <p>Post-production Information Risk Review Report includes yearly review of following topics: product and product version, review of EVRI reports, review of clinical data, review of cybersecurity, specific risk assessment, gap analysis.</p> <p><u>MDR 2017/745 - Article 10_2</u></p> <p>(Risk management system established, documented, implemented and maintained - section 3 of annex I)</p> <p>Manufacturers has established, implemented, documented, and maintained a risk management system. The risk management process is carried out as continuous activity throughout the entire lifecycle of the device. The updating frequency and triggers are defined.</p> <p><u>M8 - Documents and Records Control (MSz)</u></p> <p>Verified that procedures have been defined, documented, and implemented for the control of documents and records of both internal and external origin required by the quality management system.</p> <p>Confirmed that the medical device organization retains records and at least one obsolete copy of controlled documents for a period of time at least equivalent to the lifetime of the device, but not less than two years from the date of product release.</p> <p>Handling of documents and records is described in DEALL PQ3130.</p> <p>Controlled documents are created within BIC.</p> <p>Documentation Matrix defines types of records to be created within a process, and retention periods (minimum retention period required is 15 years, for product related records it is 30 years.</p> <p>Process Owners are reponsible for keeping conrtrolled documents up to date; this is alt least carried out by a regular review (recommended all 5 years, at least all 10 years).</p> <p>BIC contains also a change log for changes on a global and local level. Herein, changes are described.</p> <p>Australia (TGA):</p>

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	<p>Confirmed that Quality Management System documentation and records in relation to a device described in TG(MD)R Sch3 P1 1.9 are retained by the Manufacturer for at least 5 years (actually 30 years, 11 Years reflected in written Agreements between Australian Sponsor and Drägerwerk).</p> <p>Brazil (ANVISA): Verify that change records include a description of the change, identification of the affected documents, the signature of the approving individual(s), the approval date, and when the change becomes effective [RDC ANVISA 16/2013: 3.1.5]. <input type="checkbox"/> DEALL PQ3130 : Control of Documents and Records/ Lenkung von Dokumenten und Aufzeichnungen/ Records DEALL PQ3130 - en_de - 04.00 , Rev. 04.00 Confirm that the manufacturer maintains a master list of the approved and effective documents [RDC ANVISA 16/2013: 3.1.5]. <input type="checkbox"/> Corporate Procedure List Verify that electronic records and documents have backups [RDC ANVISA 16/2013: 3.1.6]. <input type="checkbox"/> if electronic records are defined, a Backup and Archive Plan is created individually case specific; Backup & Archive Plan for BIC QPS 484: Daily backups are performed; recovery point is 24 hrs. recovery Time is 4 hours. Backup storage is handled by the provider amazon web services in accordance with 27001.</p> <p>Japan (MHLW) Confirm that Quality Management System documentation and records in relation to a device are retained by the Registered Manufacturing Site for the following periods (5 years for training records and documentation) [MHLW Ministerial Ordinance No.169: 8.4, 9.3, 67, 68]: <input type="checkbox"/> 30 Years is defined anyway for product related documentation.</p> <p>United States (FDA) Verify that electronic records and documents have backups [21 CFR 820.180]. <input type="checkbox"/> Part of Software Validation</p> <p>MDR: In addition, Drägerwerk AG & Co. KGaA assumes the role of authorized representative according to MDR or MDD/MPG for Dräger manufacturers outside Europe, e.g. for Draeger Medical Systems, Inc. (USA) or Draeger India Pvt. Ltd. (India). Drägerwerk AG & Co. KGaA assumes the roles of "importer" and "distributor" for various products, acts as a "system or procedure pack producer" in accordance with the MDR, and in some constellations also acts as an original equipment manufacturer (OEM) for other medical technology manufacturers. PQ2110 A01 Template for Table of Contents of Technical Documentation</p> <p><u>M9 Management Review</u> (all auditors) 5.6; 5.1 The overall approach to MR process was explained in the presentation. The risk-based approach with Traffic light indication (red /amber /green) is in use to indicate topics which contain MR will be done and approved with relevant members of management-board. Period one year (LMR March 2023 data from March 2022 to March 2023) Management procedure is documented in DEMF CS1100, no relevant changes since previous external audit. Management reviews are conducted at planned intervals (annually) The audited management review addresses all topics required by the standards and requirements of all regulatory aspects. Main chapters of MR: Management Summary/ Quality and Objectives/ Establishing inputs/Management evaluation Main aspects of MR: Product in focus/Handling in focus/Process in focus/ System in focus. The management review report is signed by Stefanie Hirsch and Mr. Schrofner (responsible management members). KPI's (covering main processes) are defined and represented with trends in the MR: e.g. CAPA-> 80% CAPA handling in time (2022 65%/ not reached, justification given actions defined CAPA process focus topic) e.g. audits; auditplans and fulfilment; supplier audits 2022 58 planned 48 fulfilled. Responsible employees for the preparation of management review input and required attendees are defined. Quality policies and quality objectives are installed and reviewed during the management review. MR includes a review of the suitability and effectiveness of the quality policy, quality objectives and quality management system. The latest MR record from March 2023 were demonstrated – Top Management and Executive management team - CEO was present at the company. Verified that management review procedures have been documented, management reviews are being conducted at annual intervals and that they include a review of the suitability and effectiveness of the quality policy, quality objectives, and quality management system to assure that the quality management system meets all applicable regulatory requirements. Structured into Management Summary, Quality Objectives, established Review Input, Evaluation A traffic light principle for management Summary demonstrates status of Topics for the Clusters "Product in Focus", "Handling in Focus, Process in Focus + System in Focus"; Top targets and expectations last year; Only red topic was CAPA handling in Cluster "Handling in Focus"; Target Values are >80%, Current values are 65%, 48% System, 68% within 30 days, 41% CAPA Plan define within 67 days. From 7 Follow-up action items of prior year, 6 could be closed within 2023 Management Review; 1 remained open ("Handling of CAPAs"); In regards to Quality Policy and Objectives, Key issues in 2022 was "Number and Business Impact of Field Actions: Several KPIs behind target". The Q&RA responsible persons of the different Business Units and Regions report in a dotted line to Head of Q&RA in Moisinger Allee, which therefore is able to provide global input into Management Review. Since 2022, a new global web based training is available in 15 languages and the qualification has been included in the "Global Basic Profile" (for all employees). Focus 2023 for separate Business Units is approved within Management Review.</p> <p><u>The following elements were assessed specifically as examples of Management review content:</u> -Management Summary/focus topics/process KPI -Follow up actions: one action item continuation (CAPA handling), 6 closed</p>

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	<p>-Quality policy (defined in the QMH- not changed in 2022/2023, covers integrated MS) and objectives , including quarterly Quality reports, focus issues: FSCA some actions behind target regarding planned timelines- action item management reactions and further dates with focus on this topic.</p> <p>-Human Ressources and changes of responsibilities ere represented in current MR e.g. changes in Q&RA&clinical responsibilities, overview regional sales and services.</p> <p>-Focus for BU's e.g. BU Therapy launches ATLAN family</p> <p>-2023 Quality&RA initiatives (objectives): e.g. support for product portfolio (Dräger One), organizational topics. The general topics will be followed in detail during further meetings: example 1 "channel one complaint project" (global improvement project), improvement of efficacy of complaint process; example II "Labeling @Dräger: centralization of labeling topics and used tools</p> <p>-MR Inputs: product performance/Product compliance/risk Management/Usability/Handling of complaints and CAPA's/FSCA/Design changes/Internal external audits/QMS changes/performance Service, distribution and production</p> <p>For all of these Input topics it exists a One Pager to show the status of all of the topics: find the samples under records</p> <p>2023 Initiatives are documented top-down, and broken down into projects (slide 22 in Mgmt review PPT), both for Medical, Corporate and Safety. Example: Labelling @Dräger. For this project, a separate organisational structure under the Global Q&RA has been establish.</p> <p>Establishehd Management review Inputs are:</p> <ul style="list-style-type: none">- Product performance pro BU- Product Compliance incl. new/updated regulatory requirements- Product Risk management incl. Usability- Product Feedback- Handling Complaints incl. reporting to regulatory authorities- Handling CAPAs focus System and Focus Product CAPAs- Handling design Changes focus Q&RA- Handling Field actions- Performance Sourcing- Performance Production- Performance Distribution- Performance Service- External + Interbal audits- Changes Affecting QMS- Environmental, health and performance. <p>Management Review has been signed as to be Adequate and suitable quality policy & objectives, adequate and suitable QMS, Risks and Opportunities considered, Q-Targets for next year are approved, Actons and decisions are committed.</p> <p>Based especially on Action Item 4 (Product Risk Management) and 5 (Oxygen 90+), the Top mangement poved commitment by the decision to note down an action item into the action Item List, although it was not suggested by the Management review team.</p> <p>Action Item list contains a status a status indicator for the progress and completion of actions. This review is done at least bi-annually and aligned with the quarterly Q-Reports for management.</p> <p>M10 - Distribution of Devices with Appropriate Marketing Authorization (GP)</p> <p>The organization has defined and implemented controls to ensure that only devices that have received the appropriate marketing authorization are distributed or otherwise offered for commercial distribution into the applicable markets. The devices are listed the Global Matrix data sheet, which insures only the registered devices are correctly distributed in the respective region.</p> <p>To add the device to the global Country Matrix, the regional organizations shall submit the Global Matrix request the table of applicable requirements for each jurisdiction is documented to ensure the regulatory requirements are maintained.</p> <p>The physical distribution is controlled by ERP system. The Market Clearance Form is field by the Market Clearance manager and forwarded to the SAP administrator, to setup the permitted distributing regions.</p> <p>The process for maintenance of the devices in SAP (Market Clearance) was demonstrated - documented as DCGL PQ12180 -en -037-01 Rev 1 Country Matrix</p> <p>Foe registration expels for specific devices – REF to DMA+FR-1</p> <p>M11 - Management Commitment (all auditors GM version) 5.1; 5.5.3</p> <p>Based on the sampled evidence, it was observed that Top Management has demonstrated the commitment to the QMS, this particularly achieved by the provision of resources, establishment of respective processes, analysis of data and active participation in the Management review.</p> <p>E.g. needed lacks have been identified (CAPA process), topics of IRS are adressed and evaluated. Relevant roles and responsibilities are defined. Strategic quality issues are defined and followed.</p>
Reviewed documents and records (identification and revision)	<p><u>Documents (all, also M1, M8, M11):</u></p> <p>DEMF CS1100 : Management Review DEMF - CS1100 - en - 00.00 , Rev. 00.00</p> <p>DEALL HR3400 : Employee Qualification Process DEALL HR3400 - en_de - 05.00 , Rev. 05.00, last changes: implementation of some digitalization aspects; administrative changes, effectiveness checks change of head, approval of trainings adjusted, documentation of effectiveness checks integrated in trainings measure, adjustment Anlage . A01/A01/A011/A012 , global process: product and user trainings are integrated in this process.</p> <p>New personnel should be trained during the first 3 months not longer than 1 year. Some trainings ("Arbeitssicherheit" should be done on the first day).</p> <p>ODWAG/DCGL CS1000-de-07.00 Quality Manual Rev 08, 01.05.2023 including policy integrated MS</p> <p>Template Teilnehmerliste:</p> <p>DEALL HR3400 Anlage A01-en_de-0.5.00, including trainer, date, trainee, availability, effectiveness (in case of effectiveness check during training)</p> <p>Template Q-Check:</p>

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	<p>DEALL HR 3400_A13-en_de-01.00, name of employee, ID, role, description of qualifications, signature of employee and team leader</p> <p>Template individueller Einarbeitungs Plan:</p> <p>DEALL HR 3400_ xls (related information 15)</p> <p>DWAG IN4203 : Product Verification DWAG IN4203 - en - 02.00 , Rev. 02.00</p> <p>DEMF CS1100 : Management Review DEMF - CS1100 - en - 00.00 , Rev. 00.00</p> <p>DWAG CS1000 : Dräger Integriertes Managementsystem - Handbuch der Drägerwerk AG & Co. KGaA DWAG CS1000 - de - 08.00 , Rev. 08.00</p> <p>DEALL PQ3130 : Control of Documents and Records/ Lenkung von Dokumenten und Aufzeichnungen/ Records</p> <p>DEALL PQ3130 - en_de - 04.00 , Rev. 04.00</p> <p>PQ2110 A01 Template for Table of Contents</p> <p>DWAG PQ2110 : Regulatory Approval to Market Product DWAG PQ2110 - en - 03.00 , Rev. 04.00</p> <p>Management-review summary 2023- 23 March 2023</p> <p>Action Items List (from Management review) 2022</p> <p><u>Records (all, also M1, M8, M11):</u></p> <p>DCGL PQ12180 -en -037-01 Rev 1 Country Matrix</p> <p>Organisational Chart Medical Division 2023-07-01</p> <p>Core Procedures DWAG 20230914.pdf</p> <p>Audit Trail (Electronic Documentation of approval) for DCGL PQ3130-en-04 from 2022-11-25</p> <p>Audit Trail for approval of local adopted global standard: eMail communication to DCGL SE1200 "Installation & Commissioning" between Dräger Safety Equipment China and Global process owner of Drägerwerk, dated 2023-06-28</p> <p>DEALL PQ3130_A02 Documentation Matrix</p> <p>PQ3130_2023-06-29_Documented_Procedures_older_than_10_years</p> <p>Distributor agreement Dräger australia PTY Ltd. 10.08.2018</p> <p>STED_Table_of_Contents_T500.pdf / MDR106-011, compiled 2023-08-16</p> <p>Technical Documentation is kept in ClearCase Configuration Management Tool and can be manually exported to e.g. file server structure or design dossier requirements. Respective structural needs are described within PQ2110 Regulatory approval to Market</p> <p><u>M2 (GM)</u></p> <p>Tätigkeitsbeschreibung Stefanie Hirsch, 01.09.2023, signed by Toni Schrofner and Stefanie Hirsch, QRA Medical and Corporate, Purpose of function e.g. representation and awareness QM, strategic plans, integrated MS, audit programs, continuous improvement, management representative for QMS regulations: Compliance Committee and Risk committee.</p> <p>Liste ausgewählter Beauftragter im IMS, Stefanie Hirsch MR, 11.09.2023, rev 09</p> <p>PRRC's:</p> <p>Konformität der Produkte: (Kevin Dornau (BU Therapy) Marcus Vorwerk (BU WPI), Timo Harms (BU HCA) Jakob Kleissl (BU Patient Monitoring)</p> <p>TD: Kevin Dornau (BU Therapy) Marcus Vorwerk (BU WPI), Timo Harms (BU HCA) Jakob Kleissl (BU Patient Monitoring), Bettina Möbius (Central Regulatory affairs), Stefanie Hirsch (QRA)</p> <p>PMS Inverkehrbringung/Vigilance : Sonja Hilmer</p> <p>Anhang XV Kapitel 2 (Prüfprodukte): Dr Sonja Hering</p> <p><u>M3 (GM)</u></p> <p>High level description of policy in Intranet</p> <p>DCP 0005-en-040-02 Intranet including link to Quality Broschüre: aspects Quality /Environment/Employees/Society, 2019</p> <p>ODWAG/DCGL CS1000-de-07.00 Quality Manual Rev 08, 01.05.2023 including policy integrated MS</p> <p>Presentation Dräger Recertification Audit 2023, objectives/initiatives:</p> <ol style="list-style-type: none">1. Finalization of MDR program-> last steps realization (until 2024)2. QMS readiness Dräger One-> new portfolio with focus on SW connected devices.3. Regulatory management; Rapid (SAP module) migration to ARAS4. Advance regulatory knowledge/awareness5. CAPA process improvement6. External triggers: UDI/UKCA and others7. Restructuration of complaint-process (Channel One) <p>Objectives will be reviewed on a monthly base in management Team:</p> <p>One Pager RIM (3) strategy meeting on 07.09.2023 , evaluation of project status, weekly QRA standup meeting, responsible Marcus Richter, first step regulatory information management (integration from WWRD and RAPID into one platform): start 02/2021 planned finalization 07.2024, fulfillment status total project 60%, fulfilment this year 45%, top 3 topics 2023: fulfillment SW packages/user tests/ migration preparation, output e.g. low deadline performance</p> <p>IT provider action: RIM Guidance Board, last meeting 05.09.2023, e.g. some tasks will be handed over , project risk management, low resources Mediatec, responsible persons for specific resource risks</p> <p><u>M4 (GM)</u></p> <p>Organizational Chart Dräger, 01.07.2023 B Therapy/ BU Patient Monitoring/BU WPI/ BU HCA/BU Global Services</p> <p>Organizational Chart Dräger, 01.09.2023 Q&A</p> <p>Liste ausgewählter Beauftragter im IMS, Stefanie Hirsch MR, 11.09.2023, rev 09</p> <p><u>M5 (HD)</u></p> <p>DWAG CS1000-de08.00_english translation</p>

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	<p>LIST OF OUTSOURCED PROCESS 2023-08-25 revision 7</p> <p>DEMF SP 2110 Supplier Phase in and Quality Approval Rev 03.00</p> <p>DEMF SP6250: Identification and Control of Prioritized Suppliers DEMF SP6250 - en - 03.00, Rev. 03.00</p> <p>QSV Trellabo Sealing dd 11.08.2017.</p> <p>DQPE Trellabo 20.03.2023</p> <p>Audit report Trellabo PR 26356</p> <p>Audit report AB Ulax 24.03.2021</p> <p>DQPE AB Ulax 29.03.2023</p> <p>QSV AB Ulax dd 20.11.2017</p> <p>DEMF SC 513 A07 de-02.00 FAI Results MP05840 (AB Ulax) – release for series delivery.</p> <p>Draeger Australia Distribution agreement 10/08/2018</p> <p>Memorandum of Understanding Between Dräger Australia Pty and Dräger Germany Co KG 03/08/2018</p> <p>The Distribution Agreement inclusive Amendment 1 dd02.08.2019</p> <p><u>M6 (GM)</u></p> <p>Example trainings overview Bätz Johanna (01374868):</p> <p>Overview Trainingsportal (D&D) Qualifikationsprofile Dr. Bätz (System engineer): Rollenzuweisung : Mitarbeiter DWAG (e.g. „Arbeitssicherheit“/Electronical signature)/System Engineer(e.g. 606001-1 and subset of relevant processes/GLOB_ Mitarbeiter (e.g. data protection. Anti corruption , fishing)</p> <p>Q-Check 01374868, signed 17. and 18,04 2023, all trainings performed.</p> <p>Overview Trainingsportal (production) Qualifikationsprofile: Bernowitz Michael (1003945) Teamleiter (Sawina)</p> <p>Rollenzuweisung: GLOB_ Führungskraft (e.g. Anti Corruption, Tax awareness), DE Führungskraft DWAG (Arbeitssicherheit, Führung Grundlagen Leadership) ,DE Leitung Teamleiter MT (e.g. ESD , Ergonomie Basis, yearly EMV)</p> <p>Q-Check 1003945, signed by employee and Teamleader, 09.05.2023. all trainings performed, no additional comments.</p> <p>Q Check Janson (Produktionsplanerin/Teamleiterin (1002146) 2022, 22.02.2022</p> <p>DEALL HR 3400_ xls (related information 15) (1002146),actionist, Development as Leader, additional trainings shopfloor leading, communication, working time, 22.02.2022.</p> <p>Onboarding sample:</p> <p>Overview last new employee in D&D Dr. Robert Ott (0176537) (Risk Manager ventilation), onboarding 01.11.2022</p> <p>First Q Check , 05.01.2023 (1002146), signed by team leader and employee.</p> <p>Current status (1002146) TCM trainings role risk manager DWAG, open trainings funktionale Sicherheit and Cyber Security, can be finished until November 2023.</p> <p>DEALL HR 3400_ xls (related information 15), individueller Einarbeitungsplan (1002146), incl e.g. external training 14971, done 26.10.2022</p> <p>Example external resources (Brazil)</p> <p>Q check Dr. Spengler (verification Intensive care Evita V600/V800), (1372386), all defined trainings done, e.g. the Dräger process DWAG IN4203 product verification DWAG</p> <p>External consultant contract „Arbeitnehmerüberlassungsvertrag (between Dräger and qtec services)1372386 (Dr. Spengler), current version , 01.07.2023, chapter 4.1definition of role (test engineer), qualification profile-> transmitted into TCM.</p> <p><u>M7 (HD)</u></p> <p>DWAG IN 42 10 A06- 03-00 16-04-2023 Risk Policy and acceptance criteria</p> <p>Risk Management Plan Carina/ Oxylo BC 2021-01-03</p> <p>RAT (11265056) Risk Assessment Table Carina/ Oxylo BC - 2022-07-13 revision 0</p> <p>ID 11221574 PRMR Carina/ Oxylo BC Version 01 2023-07-14</p> <p>ID 11228196 RM Process review report carina _ and Oxylog Braething 29.11.2022, revision 00</p> <p>Management Review 2022-03-30</p> <p><u>M8 (MSz)</u></p> <p>See above</p> <p><u>M9, M11 (all)</u></p> <p>DEMF CS1100: Management Review DEMF - CS1100 - en - 00.00 , Rev. 00.00</p> <p>Management-review summary 2023- 23 March 2023</p> <p>Action Items List (from Management review) 2022</p> <p>Presentation Dräger Recertification Audit 2023</p> <p>Quality Policy – documented as part of the Quality manual</p> <p>DWAG site plan Moisliger Allee, current version overview</p> <p>DWAG site site plan Revalstr., current version overview, audit mainly in W23/Haus 10/MLZ</p> <p>Organizational Chart Dräger, 01.07.2023 B Therapy/ BU Patient Monitoring/BU WPI/ BU HCA/BU Global Services</p> <p>Organizational Chart Dräger, 01.09.2023 Q&A</p> <p>Manual DWAG CS1000, rev 8 effective since 01.05.2023</p> <p>Management Review 2022 – DWAG 2022-03-22, signed by Stefanie Hirsch and Mr. Schrofner</p> <p>One pager MR input 2023:</p> <p>Example One Pager CAPA: problem timely performance of CAPA’s, evaluation in red area, actions defined: management support/priorities-> currently KPI on track</p> <p>Example WPI: failure rate in target/ Complaint reliability rate only timelines not in target</p> <p>Example One Pager Therapy: problem intime execution complaints</p>

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Subsystem	Management - Quality Management System
	<p>Example One pager HCA: 3 field actions highlighted; Field failure rate slightly above target, complaint timelines not in target.</p> <p>Example One Pager Product feedback, general in target (I all feedback will be evaluated not limited to complaints)</p> <p>Example One Pager Risk management: action Item resources</p> <p>Example One pager Product compliance</p> <p>Example One Pager complaints, yellow: slightly negative trend regarding backlog and timely closing; Quality project: process redesign (channel one)</p> <p>Example Handling of field action: 40 new opened, total 48- actions defined because of big backlog</p> <p>Example One Pager Handling of Design changes: view on long-term processing changes</p> <p>Example One Pager performance Sourcing: e.g. supplier audits, Supplier PPM slightly above target (e.g. supplier for accessories)</p> <p>Example One Pager Performance of distribution: all topics on track</p> <p>Example One Pager Performance of Service: all topics on track</p> <p>Example One Pager internal and external audit: all topics on track</p> <p>Example One Pager changes affecting QMS: all topics on track, e.g. all changes in regulatory will be evaluated.</p> <p>Action List MR 2022 – Action Item List – Update 2023-09-18.xls</p> <p><u>M10 (GP)</u></p> <p>DCGL PQ12180 -en -037-01 Rev 1 Country Matrix</p>
Names and titles of persons interviewed	<p>(all other tasks)</p> <p>Stefanie Hirsch (Head of Quality & Regulatory Affairs)</p> <p>Ulf Hagedorn (Head of Integrated Management Systems Audit Management)</p> <p>Kevin Dornau (Director Quality & Regulatory Affairs Business Unit Therapy)</p> <p>Timo Harms (remote) (Director Quality & Regulatory Affairs BU HCA)</p> <p>Marcus Vorwerk (Director Quality, Regulatory Affairs and Purchasing Business Unit Workplace Infrastructure)</p> <p>Jakob Kleissl (President Program Draeger ONE & BU Patient Monitoring)</p> <p>Bettina Möbius (Head of Central Regulatory & Clinical Affairs)</p> <p>Sonia Mess (Head of Integrated Management System)</p> <p>Sonja Hillmer (Head of Post Market Surveillance)</p> <p>Marcus Schüler (Head of Q&RA Central)</p> <p>Jana Wienke (scribe) (Quality System Manager Auditing)</p> <p><u>M2, M3, M4 (GM)</u></p> <p>Stefanie Hirsch (Head of Quality & Regulatory Affairs)</p> <p>Marcus Schüler (Head of Q&RA Central)</p> <p>Jana Wienke (scribe) (Quality System Manager Auditing)</p> <p><u>M 6 (GM)</u></p> <p>Barabara Drews (HR Manager Quality Center of Expertise Labour & Employment Human Resources)</p> <p>Reinhard Zimmermann (Head of Learning Eco System, Quality & Processes Global Academy)</p> <p>Christian Elsenbach (Teamleiter R&D, System Engineering & Risk.Management, BU Therapie)</p> <p>Dirk Geisteier (Head of Production Line Respiratory Care/ Warming Therapy)</p> <p>Jana Wienke (scribe) (Quality System Manager Auditing)</p>
Products, components, or projects reviewed	Not applicable
Statement concerning conformity based on objective evidence reviewed for this subsystem	This process is effectively implemented and conforms to requirements. Management uses appropriate data to monitor and evaluate the QMS. The organizational structure and the QMS ensure the competence and qualification of personnel.

2.5.2 Device Marketing Authorization and Facility Registration, Customer Related Processes

Subsystem	Device Marketing Authorization and Facility Registration, Customer Related Processes
Audit trail records of	G. Pavlov
Area(s) visited (location, e.g., site visited)	Location # 10578 For more details related to audit location and time refer to chapter 2.2 of this report.
Audit criteria according to audit plan	<p>"Device Marketing Authorization and Facility Registration: Submission for Device Marketing Authorization and Facility Registration (MDSAP Chapter 2, Task 1, Site: 10578); (DIN)(EN) ISO 13485 - 4.1.1, 4.2.1, 5.2, 7.2.1, 7.2.3 + (DIN)(EN) ISO 9001 - 4.4, 5.1.2, 7.5.1, 8.2.1, 8.2.2, 8.4 + MDSAP - Australia - As required by MDSAP AU P0002 + MDSAP - Brazil - As required by MDSAP AU P0002 + MDSAP - Canada - As required by MDSAP AU P0002 + MDSAP - Japan - As required by MDSAP AU P0002 + MDSAP - USA - As required by MDSAP AU P0002 + MDR - Article 32, 52, Article 10.1, 10.9 ¶3 (b, j), 10.14, 10.15; Annex IX 2.2 ¶2 (c2), 2.4, 3.2; Annex XI 6.4, 7 ¶1, [MDCG 2019-9], [MPDG § 4(2)] + MDD - Article 11"</p> <p>"Device Marketing Authorization and Facility Registration: Evidence of Marketing Clearance or Approval (MDSAP Chapter 2, Task 2, Site: 10578); (DIN)(EN) ISO 13485 - 4.1.1, 4.2.1, 5.2, 7.2.1, 7.2.3 + (DIN)(EN) ISO 9001 - 4.4, 5.1.2, 7.5.1, 8.2.1, 8.2.2, 8.4 + MDSAP - Australia - As required by MDSAP AU P0002 + MDSAP - Brazil - As required by MDSAP AU P0002 + MDSAP - Canada - As required by MDSAP AU P0002 + MDSAP - Japan - As required by MDSAP AU P0002 + MDSAP - USA - As required by MDSAP AU P0002 + MDR - Article 19 & 20, Annex IV, Annex IX ch III.6, Annex XI 2, 6 + MDD - Article 11"</p> <p>"Device Marketing Authorization and Facility Registration: Notification of Changes to Marketed Devices or to the QMS (MDSAP Chapter 2, Task 3, Site: 10578); (DIN)(EN) ISO 13485 - 4.1.1, 4.2.1, 5.2, 7.2.1, 7.2.3, 7.3.9 + (DIN)(EN) ISO 9001 - 4.4, 5.1.2, 7.5.1, 8.2.1, 8.2.2, 8.3.6, 8.4, 8.5.6 + MDSAP - Australia - As required by MDSAP AU P0002 + MDSAP - Brazil - As required by MDSAP AU P0002 + MDSAP - Canada - As required by MDSAP AU P0002 + MDSAP - Japan - As required by MDSAP AU P0002 + MDSAP - USA - As required by MDSAP AU P0002 + MDR - Article 10.9 ¶1 s2, 10.9 ¶3 (a); Annex IX 2.2 ¶2 (c1, c8) + MDD - Annex II (3.2) "</p>
Brief description of processes or activities evaluated to demonstrate what was audited related to the listed key QMS documents and records reviewed below considering inputs, outputs, and measures	<p>#1 - Submission for Device Marketing Authorization and Facility Registration Verified that the medical device organization has complied with regulatory requirements to register and/or license device facilities and submit device listing information in the appropriate jurisdictions where the medical device organization markets or distributes their devices The regulatory requirements for new products are prepared in the form of four documents: - Medical Device Classification - Regulatory approval plan - List of applicable standards - List of regulatory deliverables The requirements are registered in Medical device File.</p> <p>After registration in specific countries , the market clearance is initiated: The Process for release to the marked in defined on SOP IN8071. The results documented as special form DCGL IN8071 A02 – MC form is saved as part of DHF, the product release is performed in SAP.</p> <p>The Changes to the country requirements are controlled as part of Change description. The review is performed by the regulatory teams in the respective countries. The assessment if the change is significant –is documented in PTI (Pre-tailoring Investigation) document. If the change is significant, the regulatory review is repeated.</p> <p>The product changes are assessed in PTY (Product change description) document.</p> <p>Decisions to be done in RA Process: - MD QMS - Certification Scope Check - Review of TD (DHF) by Project Manager, - Quality Assurance Manager and RA Manager. - PRRC approves DOC.</p> <p>Country specific requirements: The list of regulatory device regiments I documented as designed input The following certificate have been reviewed:</p> <p>CAN and US is managed directly; other regions are covered by Subsidiaries ore Sales Channel Partners, Acting as the regulatory correspondents. The regulatory suppliers in MDSAP countries were demonstrated: Example: New Product Introduction M11.3 CO2 sensor – M11.3_RAP Regulatory approval plan CO2 mainstream sensor M11.3 Market Clearance CO2 mainstream sensor M11.3 USA – 20232-70-20 Marc Clearance EU (including assessment of the language requirements) 2023-05-31</p> <p>SAP release to the registered countries : Part No 6873570 generated The examples for the country release: from SAP was generated on the day the audit: It was demonstrated the M11.3 CO2 sensor – it was observed the device is correctly released for all MDSAP countries and EU, but not for Brazil and Canada – this is in line with demonstrated license registration.</p> <p>Canada: Draegerwerk AG&Co Company ID 103279 , The regulatory corresponded registered Mr. Mebius from Draeger Germany, Annual medical Device License renewal demonstrated Oct 28, 2022 Canada renewal conformation by the letter from health Canada: 2022-11-09</p> <p>Registration for the established device Oxylog 3000 Plus System – Canada License 85214 verified in MDAL data base during the audit</p>

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Subsystem	Device Marketing Authorization and Facility Registration, Customer Related Processes
	<p>New device: New Product Introduction M11.3 CO2 Sensor s check the sensor is not yet repaired and not released The samples for the new was selected New Product Introduction M11.3 CO2 Sensor</p> <p>US:</p> <p>Establishment registration verified - verified from FDA data base - demonstrated: DRAEGERWERK AG & CO.KGAA GERMANY 3001104093, 2023 – Revalstrasse; production DRAEGERWERK AG & CO.KGAA GERMANY 9611500 , 2023 – Mudslinger alee - specification developer;</p> <p>510(k)</p> <p>New Product Introduction M11.3 CO2 Sensor The 510K registration verified – 510 No K221118 from 05 April 2023 (decision date) Verification of market clearance for existing product Oxylog 3000 plus - USA Class II, no longer supplied - 510K – No K103625 - from 06 Oct 2010 The product is longer available, however, active license was demonstrated from FDA webs site</p> <p>Brazil,</p> <p>The representative in Brazil is Draeger Industria e Comercio Ltd, Centre Impresarial tambore 06460-100 Sao Paulo , Brazil The Agreement with the Brazilian regulatory representative was demonstrated: Distributor agreement Drager Brazilia – 52/08/2018 1827778/ 21-1 Brazilian Good Manufacturing Practice (GMP) certificate 02.05.2024 02_DOU Importer establishment has ANVISA Draeger Industria e Comercio Ltd CNPJ :02.535.707/0001-28 – ISSN 1677—7042 Supplement 108</p> <p>Device registration M11.3 CO2 Sensor – not yet completed in the moment of the audit, in preparation ANVISA Device certificate Oxylog 3000 plus - Brazil III BRA20/01250 10/08/2020</p> <p>Australia</p> <p>The registered Sponsor is Dräger Australis PTY , Noting Hill. Vic 3168 Australia The Distributor agreement – contains the responsibility of the Australian sponsor Distributor Agreement Drager Australia PTY 10.08.2018.</p> <p>New Product Introduction M11.3 CO2 Sensor – ARTG license: M11.3 CO2 Sensor 414435 registered from 24/07/023 Medical device Class IIa</p> <p>Oxylog 3000 plus License ARTG 169507 registered from 01/03.2010 demonstrated from Australia regulatory authority web site during the audit</p> <p>Japan</p> <p>The MAH for Japan is Draeger Japan LTD The Distributor Agreement Dräger Japan 27 may 2019 The Facility registration was demonstrated: 13B1X00173 from 2-13-17</p> <p>The manufacturing facilities are registered with respective registration numbers: Dräger GMBH – Moisliger Alea BG21300929 Drager GmbH – Revalstrasse BG21300930</p> <p>Device registration for JAPAN Registration Certificate japan Oxylog 3000 plus Class III 22300BZX00184000</p> <p><u>#2 - Evidence of Marketing Clearance or Approval</u> It could be confirmed that the medical device organization has received appropriate marketing clearance or approval in the regulatory jurisdictions where the medical device organization markets their devices. Ref to task DMA+FR-1 for specific examples of device market clearance for MDSAP jurisdictions</p> <p><u>#3 - Notification of Changes to Marketed Devices or to the QMS</u> Verified during the audit that the medical device organization has identified changes to marketed devices or the quality management system which require notification to regulatory authorities.</p> <p>Country specific requirements: Australia / Brazil / Canada / Japan / US Following notification of changes in each jurisdiction were demonstrated: The change of the device Savina 300 (Select, Classic, NIV) New Software Version 5.02.01 The change is documented under Package Number PKG-2022-001602 PKG-2022-001602 Software Version 5.02.01 Bugfix Feb 23, 2023</p> <p>Japan</p> <p>The regulatory assessment japan - necessary action internal assessment => immediate product release Regulatory approval planning Savina SW 02.02.01 Ver 02 31/03/2023</p> <p>USA – approval necessary – letter to File demonstrated as per 510K requirements: USA Letter to file Change Software Savina SW 02.02.01 Ver 02 31.03.2023</p>

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Subsystem	Device Marketing Authorization and Facility Registration, Customer Related Processes
	<p>Australia Assessment performed – no regulatory submission needed 2023-03-01</p> <p>Canada the change will be covered Annual renewal of Market registration</p> <p>Brazil according to internal Tool WWRD - no regulatory approval necessary</p> <p>Australia The Internal documentation - no submission</p> <p>MDR 2017/745 - Article 31 Process for registration of manufacturers, authorized representatives and importers (as soon as electronic system to create the single registration number is available) The regulatory requirements are documented in the technical File Tale of content The devices are registered in DMIDS Dutch Information and Databank system BFARM data base: rev=cord was demonstrated for CO2 Detector 000053337 BFARM registration CO2 Sensor 2023-01-23</p> <p>The facility registration in EUDAMED was demonstrated for 3 roles: DE-MF-000005329 Legal Manufacturer DE-IM-000008374 Importer DE-AR-000005330 – Legal representative,</p> <p>EU: assessment of impact of significance of change: Regulatory Change assessment Europe Savina 300 2023-03-01</p>
Reviewed documents and records (identification and revision)	DWAG PQ2110 : Regulatory Approval to Market Product DWAG PQ2110 - en - 03.00 , Rev. 03.00 IN8071 EN02 market Clearance
Names and titles of persons interviewed	Bettina Möbius, Head of Central Regulatory & Clinical Affairs Kervin Schlünß, Country Expert Regulatory Affairs Carolin Bombeck, Country Expert Regulatory Affairs Volker Ständer, Head of Process & Project Management Office Ruven Brenzek (scribe) Regulatory Affairs Support
Products, components, or projects reviewed	Savina SW 02.02.01 M11.3 CO2 Sensor Oxylog 3000 plus
Statement concerning conformity based on objective evidence reviewed for this subsystem	This process is effectively implemented and conforms with requirements

2.5.3 Measurement, Analysis, and Improvement, CAPA and Internal Audit

Subsystem	Measurement, Analysis, and Improvement - CAPA and Internal Audit
Audit trail records of	Martin Szepannek / Gabriele Mousset / Honorata Donnermair
Area(s) visited (location, e.g., site visited)	Location # 10578 For more details related to audit location and time refer to chapter 2.2 of this report.
Audit criteria according to audit plan	<p>"Measurement, Analysis and Improvement: Procedures for Measurement, Analysis, and Improvement of QMS Effectiveness and Product Conformity (MDSAP Chapter 3, Task 1, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 8.1, 8.2.1, 8.2.6, 8.5 + (DIN)(EN) ISO 9001 - 7.5.1, 8.5.5, 8.6, 9.1.1, 9.1.2, 10 + MDSAP - Australia - TG(MD)R Sch3 P1 1.4(3)(a),(b), (5)(b)(iii), (f) + MDSAP - Brazil - RDC ANVISA 16/2013: 5.3.1, 7.1, 7.2 + MDSAP - Japan - MO169: 6, 54, 55-1, 58, 59, 62, 63, 64; [Old: 6, 54, 55, 58, 59, 62, 63, 64] + MDSAP - USA - 21 CFR 820.100(a) + MDR - Article 10.9 ¶3 (m); Annex IX 2.2 ¶2 (b2, e); Annex XI 13 + MDD - Annex II (3.2)"</p> <p>"Measurement, Analysis and Improvement: Sources of Quality Data (MDSAP Chapter 3, Task 2, Site: 10578); (DIN)(EN) ISO 13485 - 7.5.4, 8.1, 8.2.1, 8.2.6, 8.4 + (DIN)(EN) ISO 9001 - 8.5.5, 8.6, 9.1.1, 9.1.2, 9.1.3 + MDSAP - Australia - TG(MD)R Sch3 P1 1.4(3)(a),(b), (5)(b)(iii), (f) + MDSAP - Brazil - RDC ANVISA 16/2013: 7.1.1.1, 9.1 + MDSAP - Japan - MO169: 43, 54, 55-1, 58, 59, 61; [Old: 43, 54, 55, 58, 59, 61] + MDSAP - USA - 21 CFR 820.100(a) + MDR - Article 10.9 ¶3 (m); Annex IX 2.2 (b); Article 88 + MDD - Annex II (3.2), Annex VI (3.2)"</p> <p>"Measurement, Analysis and Improvement: Investigation of Nonconformity (MDSAP Chapter 3, Task 3, Site: 10578); (DIN)(EN) ISO 13485 - 8.5.2 + (DIN)(EN) ISO 9001 - 10.2 + MDSAP - Australia - TG(MD)R Sch3 P1 1.4(3)(a),(b), (5)(b)(iii), (f), TG(MD)R Sch1 P1 2 + MDSAP - Brazil - RDC ANVISA 16/2013: 2.4, 6.5.1, 7.1.1.2 + MDSAP - Japan - MO169: 63 + MDSAP - USA - 21 CFR 820.100 (a)(2) + MDR - Article 10.9 ¶3 (l) + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>"Measurement, Analysis and Improvement: Investigation of Potential Nonconformity (MDSAP Chapter 3, Task 4, Site: 10578); (DIN)(EN) ISO 13485 - 8.5.3 + (DIN)(EN) ISO 9001 - 0.3.3, 6.1, 10.1, 10.3 + MDSAP - Australia - TG(MD)R Sch3 P1 1.4(3)(a),(b), (5)(b)(iii), (f), TG(MD)R Sch1 P1 2 + MDSAP - Brazil - RDC ANVISA 16/2013: 2.4, 7.1.1.1 + MDSAP - Japan - MO169: 64 + MDSAP - USA - 21 CFR 820.100(a)(2) + MDR - Article 10.9 ¶3 (l) + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>"Measurement, Analysis and Improvement: Correction, Corrective Action, and Preventive Action (MDSAP Chapter 3, Task 5, Site: 10578); (DIN)(EN) ISO 13485 - 8.2.1, 8.2.5, 8.3.1, 8.5.2, 8.5.3 + (DIN)(EN) ISO 9001 - 0.3.3, 6.1, 8.5.5, 9.1.1, 9.1.2, 10.1, 10.2, 10.3 + MDSAP - Australia - TG(MD)R Sch1 P1 2, TG(MD)R Sch3 P1 1.4(3)(a),(b), (5)(b)(iii), (f) + MDSAP - Brazil - RDC ANVISA 16/2013: 2.4, 6.5, 7.1.1.3, 7.1.1.4, 7.1.1.5 + MDSAP - Japan - MO169: 55-1, 57, 60-1, 63, 64; [Old: 55, 57, 60, 63, 64] + MDSAP - USA - 21 CFR 820.100(a)(3), 820.100 (a)(4), 820.100(a)(6), 820.100(b) + MDR - Article 10.9 ¶3 (l) + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>"Measurement, Analysis and Improvement: Assessment of Design Change Resulting from Corrective or Preventive Action (MDSAP Chapter 3, Task 6, Site: 10578); (DIN)(EN) ISO 13485 - 7.1, 7.3.9 + (DIN)(EN) ISO 9001 - 8.1, 8.3.6, 8.5.6 + MDSAP - Australia - TG(MD)R Sch1 P1 2 + MDSAP - Brazil - RDC ANVISA 16/2013: 2.4, 4.1.10 + MDSAP - Japan - MO169: 26, 36-1; [Old: 26, 36] + MDSAP - USA - 21 CFR 820.30(f), 820.30(g) + MDR - Article 10.9 ¶1 s2, 10.9 ¶3 (a); Annex IX 2.2 ¶2 (c1, c8) + MDD - Annex II (3.2)"</p> <p>"Measurement, Analysis and Improvement: Assessment of Process Change Resulting from Corrective or Preventive Action (MDSAP Chapter 3, Task 7, Site: 10578); (DIN)(EN) ISO 13485 - 4.1.2, 4.1.4, 4.1.6, 4.2.1, 7.1, 7.5.2, 7.5.6, 7.5.7 + (DIN)(EN) ISO 9001 - 4.4, 7.5.1, 8.1, 8.4, 8.5.1 + MDSAP - Australia - TG(MD)R Sch1 P1 2; Sch3 P1 1.5(4); TG(MD)R Sch3 P1 1.5(2) + MDSAP - Brazil - RDC ANVISA 16/2013: 2.4, 5.6, 7.1.1.4 + MDSAP - Canada - CMDR 1, 34 + MDSAP - Japan - MO169: 5-2, 5-4, 5-6, 6, 26, 29, 41, 45, 46; [Old: 5, 6, 26, 41, 45, 46] + MDSAP - USA - 21 CFR 820.100(a)(4), 820.100(a)(5), 820.70(b), 820.75(c) + MDR - Annex IX 2.2 ¶2 (d); Annex XI 6.2 ¶2, 12 + MDD - No specific requirements"</p> <p>"Measurement, Analysis and Improvement: Identification and Control of Nonconforming Product (MDSAP Chapter 3, Task 8, Site: 10578); (DIN)(EN) ISO 13485 - 8.3.1, 8.3.2 + (DIN)(EN) ISO 9001 - 8.7, 10.2 + MDSAP - Australia - TG(MD)R Sch3 P1 1.4(5)(b)(iii) + MDSAP - Brazil - RDC ANVISA 16/2013: 6.5, 7.1.1.6 + MDSAP - Japan - MO169: 60-1, 60-2; [Old: 60] + MDSAP - USA - 21 CFR 820.90(a) + MDR - Annex IX 2.2 ¶2 (b2); Annex XI 6.2 ¶2, 12 ¶1"</p> <p>"Measurement, Analysis and Improvement: Action Regarding Nonconforming Product Detected After Delivery (MDSAP Chapter 3, Task 9, Site: 10578); (DIN)(EN) ISO 13485 - 8.3.3, 8.5.2 + (DIN)(EN) ISO 9001 - 8.7, 10.2 + MDSAP - Australia - TG(MD)R Sch1 P1 2, TG(MD)R Sch3 P1 1.4(3)(a),(b), (5)(b)(iii), (f) + MDSAP - Brazil - RDC ANVISA 16/2013: 2.4, 7.1.1.8 + MDSAP - Japan - MO169: 60-3, 63; [Old: 60, 63] + MDSAP - USA - 21 CFR 820.100(a) + MDR - Article 10.9 ¶3 (k), 10.12; Article 87- 92 + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>"Measurement, Analysis and Improvement: Internal Audit (MDSAP Chapter 3, Task 10, Site: 10578); (DIN)(EN) ISO 13485 - 6.2, 8.2.4 + (DIN)(EN) ISO 9001 - 7.2, 7.3, 9.2 + MDSAP - Australia - TG(MD)R Sch3 P1 1.4(5)(b)(iii) + MDSAP - Brazil - RDC ANVISA 16/2013: 7.3 + MDSAP - Japan - MO169: 22, 23, 56 + MDSAP - USA - 21 CFR 820.22, 820.100 + MDR - Annex IX 2.2 ¶2 (b2); Annex XI 6.2 ¶2 + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>"Measurement, Analysis and Improvement: Information Supplied for Management Review (MDSAP Chapter 3, Task 11, Site: 10578); (DIN)(EN) ISO 13485 - 5.6.2 + (DIN)(EN) ISO 9001 - 9.3.1 + MDSAP - Australia - TG(MD)R Sch3 P1 1.4(5)(b)(iii) + MDSAP - Brazil - RDC ANVISA 16/2013: 2.2.6, 7.1.1.7 + MDSAP - Japan - MO169: 19 + MDSAP - USA - 21 CFR 820.100 (a)(7) + MDR - Article 10.9 ¶1 S2; Annex IX 2.2 ¶2 (c8)"</p> <p>"Measurement, Analysis and Improvement: Evaluation of Information from Post-Production Phase, Including Complaints (MDSAP Chapter 3, Task 12, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 7.2.3, 7.5.4 (a), 8.2.1, 8.2.2, 8.5.1 + (DIN)(EN) ISO 9001 - 7.5.1, 8.2.1, 8.5.5, 9.1.2, 10.1, 10.3 + MDSAP - Australia - TG(MD)R Sch1 P1 2, Sch3 P1 1.4(3), 1.4(5)(b)(iii) & 1.4(5)(f) + MDSAP - Brazil - RDC ANVISA 16/2013: 7.2 + MDSAP - Canada - CMDR 57-58 + MDSAP - Japan - MO169: 6, 29, 43, 55-1, 55-2, 62; [Old: 6, 29, 43, 55, 62] + MDSAP - USA - 21 CFR 820.198 + MDR - Article 10.9 ¶3 (j), 10.10; Annex IX 2.1 ⑤⑨, 2.2 ¶2 (b2); Annex XI 6.2 ¶2; Article 83 - 86 + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>"Measurement, Analysis and Improvement: Communications with External Parties Involved on Complaints (MDSAP Chapter 3, Task 13, Site: 10578); (DIN)(EN) ISO 13485 - 4.1.5, 7.4.1, 8.3.1 + (DIN)(EN) ISO 9001 - 4.4, 8.4, 10.2 + MDSAP - Brazil - RDC ANVISA 16/2013: 7.1.1.6 + MDSAP - Japan - MO169: 5-5, 37, 60-1; [Old: 5, 37, 60] + MDSAP - USA - 21 CFR 820.100(a)(6) + MDR - Annex IX 2.2 ¶2 (b2); Annex XI 6.2 ¶2, 12 ¶1 + MDD - Article 10"</p> <p>"Measurement, Analysis and Improvement: Evaluation of Complaints for Adverse Event Reporting (MDSAP Chapter 3, Task 14, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 7.2.3, 8.2.3 + (DIN)(EN) ISO 9001 - 4.4, 8.2.1, 8.4, 8.5.5 + MDSAP - Australia - TG(MD)R Sch3 P1 1.4(3)(c) + MDSAP - Brazil - RDC ANVISA 16/2013: 7.1.1.8, RDC ANVISA 67/2009 + MDSAP - Canada - CMDR 59-61.1 + MDSAP - Japan - MO169: 6, 29, 55-3; [Old: 6, 29, 62] + MDSAP - USA - 21 CFR 803 + MDR - Article 10.9 ¶3 (k), 10.12, 10.13; Article 80, 87, 88, 89, 94 + MDD - Article 10"</p> <p>"Measurement, Analysis and Improvement: Evaluation of Quality Problems for Advisory Notices (MDSAP Chapter 3, Task 15, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 7.2.3, 8.3.3 + (DIN)(EN) ISO 9001 - 4.4, 8.2.1, 8.4, 8.7 + MDSAP - Australia - TG(MD)R Sch3 P1 1.4(3)(c) + MDSAP - Brazil - RDC ANVISA 16/2013: 7.1.1.8, RDC ANVISA 23/2012 + MDSAP - Canada - CMDR 63-65.1 + MDSAP - Japan - MO169: 6, 29, 60-3; [Old: 6, 29, 60] + MDSAP - USA - 21 CFR 806, 820.100(a) + MDR - Article 10.9 ¶3 (k), 10.12; Article 80, 87, 88, 89, 94 + MDD - Article 10"</p> <p>"Measurement, Analysis and Improvement: Top Management Commitment to Measurement, Analysis, and Improvement Process (MDSAP Chapter 3, Task 16, Site: 10578); (DIN)(EN) ISO 13485 - 4.1.3, 5.2, 8.1, 8.5.1 + (DIN)(EN) ISO 9001 - 4.4, 5.1.2, 8.4, 9.1.1, 10.1, 10.3 + MDSAP - Brazil - RDC ANVISA 16/2013: 2.2.1 + MDSAP - Japan - MO169: 5-3, 11, 54, 62; [Old: 5, 11, 54, 62] + MDR - Article 10.9 ¶3 (c) + MDD - Annex II (2, 3.1)"</p>
Brief description of processes or activities evaluated to demonstrate what was audited related to the listed key QMS documents and records reviewed below considering inputs, outputs, and measures	<p>MAI 1 - Procedures for measurement, analysis and improvement (GM) 8.1:8.2.1; 8.2.6; 8.5 => Focus on System</p> <p>Affected roles: Requester/Responsible Person/ CAPA Reviewer/CAPA Owner</p> <p>The process DEMF PQ3300 describes the evaluation of system CAPA's</p> <p>CAPA triggers are e.g. audits/feedback/issues/proposals/complaints/data-analysis.</p> <p>Requester and Responsible person have to make an immediate decision whether direct measures would be necessary. The quality manager will be responsible for further investigation steps and for the CAPA decision. The issue can be followed as "documented action" or as full CAPA. The documentation from here will be in Track Wise.</p> <p>Main CAPA triggers: Major NC's from audit/issue with effect on efficacy of system and increase of risk for health or environment or missing process descriptions or external requirements.</p> <p>Each case will be evaluated regarding risk within the risk form: PQ3300 – A01 Risk evaluation template. Following aspects will be evaluated: Environment, Employees, Health of patients or users, integrated Managementsystem /certification, and product conformity. If there is any risk identified a description and evaluation of the situation have to be documented. Based on this evaluation the decision for further processing "CAPA" or documented action " will be done.</p> <p>For each CAPA (not for "documented action") a CAPA plan should be provided and the CAPA plan have to be checked and approved by CAPA reviewer. The CAPA reviewer will take the decision whether the planned actions are appropriate to the risk.</p>

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	<p>For both -CAPA and "documented action"- root cause and risk analysis, actions, corrective actions and effectiveness checks have to be defined and implemented.</p> <p>It is differentiated in CAPA procedures between quality problems and nonconforming product. Two different procedures are in place. The sources and impact of all issues will be analyzed and documented.</p> <p>DEMF/DCS PQ2510 product CAPA DEMF PQ3300 system CAPA</p> <p>Furthermore, the handling of nonconforming product are defined in: DEMF SC6110 : Behandlung von Abweichungen in der Produktion DEMF SC6111 : Lenkung von fehlerhaftem Material</p> <p>These procedures are linked to each other. For each documented action (issue) and CAPA correction and corrective - (preventive) action) is defined.</p> <p>USA: Verify procedures ensure that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of problems [21 CFR 820.100(a)(6)]. Confirm procedures provide for the submission of relevant information on identified quality problems, as well as corrective and preventive actions, for management review [21 CFR 820.100(a)(7)].</p> <p>The manufacturer ensures that information about quality problems or nonconforming products are properly disseminated to those directly involved in the maintenance of product quality and to prevent occurrence of such problems. This is assured via regular Quality Boards meetings in each BU or product family/PQB.</p> <p>During the audit the auditor focused according to audit plan on system related samples.</p> <p>The CAPA's (Systems and product) are analyzed and results provided for MR: see One pager CAPA</p> <p>Brazil: Verify that the manufacturer has ensured that information about quality problems or nonconforming products are properly disseminated to those directly involved in the maintenance of product quality and to prevent occurrence of such problems [RDC ANVISA 16/2013: 7.1.1.6].</p> <p>The manufacturer ensures that information about quality problems or nonconforming products are properly disseminated to those directly involved in the maintenance of product quality and to prevent occurrence of such problems. This is assured via regular Quality Boards meetings in each BU or product family/PQB.</p> <p>During the audit the auditor focused on system related samples.</p> <p><u>MAI 1 - Procedures for measurement, analysis and improvement (GM) => Focus on Product</u> The process to measure, analysis and improve the QMS is established and documented. The process describes the evaluation of the data from the product. Investigations are conducted to identify the cause of the detected and potential nonconformities. Input from various sources, which may represent a complaint is registered, and investigated. The investigation is conducted as part of NC, CAPA and supplier quality processes in line with requirements of respective SOPs. The CAPA criteria are defined (risk negative impact on product safety, caused death or injury, cybersecurity unacceptable risk, not fulfilled regulatory requirements) when an action should be evaluated. In case no action is started this will be documented. CAPA can be also started without the intervention of the Quality Board, depending on the meeting of the criteria for CAPA. When CAPA are set and implemented, these should be evaluated for effectiveness, including the root cause analysis. All will be documented in the product CAPA in TrackWise. The roles and responsibilities are defined. The timeline for processing is defined e.g.: 7 days for initial analysis, 60 days for implementation of CAPA plan. It is possible to include annexes in the documentation. If the CAPA has a systematic cause, there is a link to the system CAPA process and the other way around.</p> <p>The KPIs are defined for CAPA process and are monitored in monthly meeting. The last 12-month report was reviewed states the 78% of CAPAs are completed withing set up due target. 22 CAPA were completed in 2022. In time completion rate: risk assessment 89%, Investigation 41%, completion 65%The KPIs are splitted in BU and shows CAPA status: ongoing, completed, overdue or effectiveness check overdue.</p> <p>(Brazil, US) Data will be analysed in Quality Boards, these will be managed by the product quality manager. This information includes statistical information or individual cases e.g.: complaints. The decision to start a CAPA will be taken in the Product quality board and documented. It is taken based on three criteria. When CAPA actions are marked as completed and will be closed only when the effectiveness check is completed.</p> <p>Additional country-specific requirements: Brazil (ANVISA): The manufacturer ensures that information about quality problems or nonconforming products are properly disseminated to those directly involved in the maintenance of product quality and to prevent occurrence of such problems. This is assured via Quality Boards meeting as describe above.</p> <p>United States (FDA): The Procedure ensures that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of problems – This performed via Quality board mechanism and statistical approach as discussed above</p>

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	<p>During the audit the auditor focused on product related samples.</p> <p><u>MAI 2 - Sources of Quality data (GM) 8.4</u> Appropriate sources of quality data have been identified for input into the measurement, analysis and improvement process, including customer complaints, feedback, service records, returned product, internal and external audit findings, nonconformities from regulatory audits and inspections, and data from the monitoring of products, processes, nonconforming products, and suppliers. This have been verified with the last MR where all these data have been verified. (One pager's based on the above mentioned topics have been audited) Data from these sources are accurate and analyzed according to a documented procedure -DEMF PQ8050 : Statistical Techniques - for the use of valid statistical methods (where appropriate) to identify existing and potential product and quality management system nonconformities that may require corrective or preventive action.</p> <p><u>MAI 2 - Sources of Quality data (HD) 8.4</u> Input from various sources, which may represent a complaint is registered, and investigated. The investigation is conducted as part of NC, CAPA and supplier quality processes in line with requirements of respective SOPs. Further sources such as trends, production quality control data, service records, audit finding etc. are analysed and evaluated. Complain trainings, warranty trending, FFR rates and Supplier PPM rate evaluations are performed in quarterly meetings.</p> <p><u>MAI3 - Root cause analysis of detected NC's (GM) 8.5.2</u> Investigations are conducted to identify the underlying cause(s) of detected nonconformities, where possible. Several cases have been audited as samples to verify, that cause analysis have been conducted: #122371/#122373/#122374/#122377/#122378 Investigations are commensurate with the risk of the nonconformity. This is asured by conducting risk analysis for each issue "documented action" or "CAPA", system and product related as described under MAI 1 Additional Sample risk analysis audited:#103501</p> <p>Monitoring and measurement of processes (8.2.5), product (8.2.6)</p> <p><u>MAI 3 – Investigation of Nonconformity (HD) 8.5.2</u> Investigation of Nonconformity & Investigation of Potential Nonconformity</p> <p>The process is established. Investigations are conducted to identify the (underlying) cause of the detected nonconformities. Several established methods for root cause analysis are used, such as 5W or Fishbone. Investigations are proportional to the risk of the nonconformity (risk-based approach), criteria are defined e.g.: Go as far as possible if following applies: -Death or injury -Complain indicate new trend -Client or authority request deep investigation -Complain classified as AE</p> <p>Potential non-conformities are also detected and analysed accordingly. The root cause is determined for all CAPA.</p> <p>PR 124066 dd. 03.11.2022– Brazil. The foreign body in expiratory membrane of Babylog VN600 the device was not in use. Complain investigation report states that this is impurity of manufacturing process. It is in ex breathing membrane and cannot go to the patient. The risk is known. Action communication with supplier.</p> <p>PR 1321136 dd. 21.06.2023 USA - FoA (Warranty) anaesthesia circuit flex 6. No patient involvement. Circuit cracking/tearing impacts the ventilation of patient (reduced breathing). Risk is known and evaluated no new / higher risk. An DCR (design change request) was started to evaluate if other material could ensure more mechanical force DCR 2023 – 004142.</p> <p>PR 126323 dd. 06.12.2022 Canada- disposable birthing hose. The investigation was performed no new or unknown risk.</p> <p>PR 126748 dd. 08 12.2022 Australia ECG Mono Leads 4.1m MP0531. The cable caused pressure injury by the patient. The new mono lead has higher dimeter as the old version. DCR 2023-001245 it was decided to update the risk management file including update of IFU (new IFU) as the risk was not identified. The IFU update with proper use of cables.</p> <p><u>MAI 4 - Investigation of potential NC's (GM) 8.5.3</u> Potential non-conformities regarding product and product processes are analyzed within FMEA's. Sample of FMEA's have been audited: FMEA PIA-PIA2 Investigations are conducted to identify the (underlying) cause of the detected nonconformities. Several established methods for root cause analysis are used in general, such as 5W or Fishbone. Investigations are commensurate with the risk of the nonconformity. Furthermore, during each MR an evaluation of internal audit results related to QMS processes will be done and documented to estimate whether any new or higher risk related to main QMS processes can be assumed derived from current internal audit performance. Evaluation of internal audit results of MR 2023 have been audited.</p> <p>Corrective action (8.5.2), Preventive action (8.5.3)</p>

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	<p><u>MAI 4 - Investigation of potential NC's (HD) 8.5.3</u> The investigation of potential non-conformities is documented and performed in the same way as for non-conformities, as discussed in Task 3. CAPA process is defined in SOP PQ2510 and contains criteria to raise a CAPA. The inputs for the product quality boards are prepared by the report owner, based on the criteria defined in the process. There is an investigation plan in place. This data includes information from failure rate in production, installation, complaints, failure of parts, among others. CAPAs are also triggered by non-conformities detected in other processes. There is the possibility to close a CAPA without actions, the rationale has to be documented.</p> <p><u>MAI 5 - Confirm corrections, corrective actions and preventive actions (GM) 8.5.2; 8.5.3</u> Corrections, corrective actions, and preventive actions for system CAPA are defined and implemented according to the documented procedure – DEMF PQ3300. Inputs and outputs are defined. CAPA triggers, criteria and responsibilities are defined. See MAI 1 Systems CAPA triggers are e.g.: management review, processes, procedures, records of services, systematic problems, etc. The CAPAs are documented in Track Wise. Some events according to the CAPA criteria are documented as "Documented Action" and not as CAPA. The investigation process for "documented action" is not that extensive as by the CAPA. It requires a "documented action response report" after investigation. Each "documented action" can be escalated to CAPA. Each case will be evaluated regarding risk within the risk form: PQ3300 – A01 Risk evaluation template. Following aspects will be evaluated: Environment, Employees, Health of patients or users, integrated Managementsystem /certification, and product conformity. If there is any risk identified a description and evaluation of the situation have to be documented. Based on this evaluation the decision for further processing "CAPA" or documented action " will be done. For each CAPA (not for "documented action") a CAPA plan should be provided and the CAPA plan have to be checked and approved by CAPA Reviewer. The CAPA reviewer will take the decision whether the planned actions are appropriate to the risk. For both CAPA and documented action root cause and risk analysis, actions, corrective actions and effectiveness checks have to be defined and implemented. It is differentiated in CAPA procedures between quality problems and nonconforming product. Two different procedures are in place. The sources and impact of all issues will be analyzed and documented.</p> <p><u>MAI 5 - Confirm corrections, corrective actions and preventive actions (HD) 8.5.2; 8.5.3</u> Correction, Corrective Action, and Preventive Action Corrections, corrective actions, and preventive actions for product CAPA are defined and implemented according to the documented procedure DCS PQ2510-013. Inputs and outputs are defined. CAPA triggers, criteria and responsibilities are defined. The CAPA criteria are defined (risk negative impact on product safety, caused death or injury, cybersecurity unacceptable risk, not fulfilled regulatory requirements) when an action should be evaluated The CAPAs are documented (Track Wise). Some events according to the CAPA criteria are documented as Documented Action and not as CAPA. The investigation process is not that extensive as by the CAPA. It requires a Documented Action Response Report after investigation. Each Documented Action can be escalated to CAPA. The timeline for processing is defined e.g.: 7 days for initial analysis, 60 days for implementation of CAPA plan. It is possible to include annexes in the documentation. If the CAPA has a systematic cause, there is a link to the system CAPA process and the other way around. The KPIs are defined for CAPA process and are monitored in monthly meeting. The last 12-month report was reviewed states the 78% of CAPAs are completed withing set up due target. The KPIs are splitted in BU and shows CAPA status: ongoing, completed, overdue or effectiveness check overdue. For reviewed CAPA examples see records</p> <p><u>MAI 6 - Assessment of Design Change resulting from Corrective or Preventive Action (HD)</u> WWhen the CAPA is outcome in Design change – Change Control process is involved. The routes for design changes are possible depends on the significant of changes are described in procedure. Relevant steps are documented. Wen DCR is accepted the – PKG (Package) will be created including the list of deliverables. Further steps are investigation, plan DC, implement DC, execute DC, transfer and DC closure. PR 126748 dd. 08.12.2022 Australia ECG Mono Leads 4.1m MP0531. The cable caused pressure injury by the patient. The new mono lead has higher diameter as the old version. DCR 2023-001245 it was decided to update the risk management file including update of IFU (new IFU) as the risk was not identified. The IFU update with proper use of cables. DCR 2021-006406 PKG 2020-002624 EHF (DCR flow sensor). The flow sensor produced previously by supplier was transfer to the DWAG production line in Lübeck. As part of this change also the color of the housing was changed as well as slight changes in the housing shape.</p> <p><u>MAI 7 - Process change -> revalidation (GM) 7.5.6; 8.5.2</u> When a corrective or preventive action results in a process change, the process change is assessed to determine if any new risks to the product are introduced.</p>

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	<p>This is assured with approval process DEMF SC6500, which defines for creation, changes and approvals of process descriptions.</p> <p>Risk evaluation :</p> <p>Samples process change with DEMF SC6500: Anlage A02: DEMF SC6500: Anlage A02 ATLAN Arbeitsplatz SM2 SM1 DEMF SC6500: Anlage A02 Babyleo Arbeitsplatz SM2 SM1,</p> <p>Canada:</p> <p>Verify that the manufacturer has a process or procedure for identifying a "significant change" to a class III or IV device. Verify that information about "significant changes" is submitted in a medical device license amendment application [CMDR 1, 34].</p> <p>Requirements implementation Verified and described with two audited samples: DEMF SC6500: Anlage A02 zu Dokumentation von Produktionsprozessen, 02, point 4. „Bewertung der Änderungen“ including question „Aktualisierung Process FMEA „ and „ Verification needed“ and Validierung erforderlich“ . Additional it is assured that if any change in STED of products is needed (change in PQ 2110), that the Design change process is applicable and respective reports will be done. Assessment of changes are triggered and the following SOP's and instructions have to be followed for decision about significant change and related duties: DWAG PQ2110 : Regulatory Approval to Market Product DWAG PQ2110 - en - 04.00 , Rev. 04.00 A08 DWAG PQ2110 Assessment of changes to medical devices, rev 04.00 – specifics of all MDSAP countries are inserted (Canada/Brazil/Japan/Australia/USA/Europe) and supported by change overview matrix with further country specifics of all MDSAP countries helping for the decision whether there is a significant change. If any significant change is evaluated a regulatory affairs manager will be informed for conduction of all further needed steps related to different MDSAP areas affected</p> <p>Australia:</p> <p>Confirm that the Manufacturer's procedure for dealing with substantial changes to a critical process (e.g. sterilization, processing materials of animal origin, processing materials of microbial or recombinant origin, or processes that incorporate a medicinal substance in a medical device), requires the Manufacturer to notify the Auditing Organization of their plans before implementing a change to a critical process. The Auditing Organization is to assess the proposed change before implementation by the Manufacturer, to determine if the requirements of the relevant conformity assessment procedure will still be met after the change. [TG(MD)R Sch3 P1 1.5(2)].</p> <p>If the Manufacturer is also a holder of a TGA Conformity Assessment Certificate, then the Manufacturer is also required to notify the TGA of these changes, prior to implementation.</p> <p>Requirements implementation Verified and described within two audited samples: DEMF SC6500: Anlage A02 zu Dokumentation von Produktionsprozessen, 02, point 4. „Bewertung der Änderungen“ including question „Aktualisierung Process FMEA „ and „ Verification needed“ and Validierung erforderlich“ . Additional it is assured that if any change in STED of products is needed (change in PQ 2110), that the Design change process is applicable and respective reports will be done. Assessment of changes are triggered and the following SOP's and instructions have to be followed for decision about significant change and related duties: DWAG PQ2110 : Regulatory Approval to Market Product DWAG PQ2110 - en - 04.00 , Rev. 04.00 A08 DWAG PQ2110 Assessment of changes to medical devices, rev 04.00 – specifics of all MDSAP countries are inserted (Canada/Brazil/Japan/Australia/USA/Europe) and supported by change overview matrix with further country specifics of all MDSAP countries helping for the decision whether there is a significant change. If any significant change is evaluated a regulatory affairs manager will be informed for conduction of all further needed steps related to different MDSAP areas affected</p> <p>Japan:</p> <p>Confirm that when the Registered Manufacturing Site plans to make a significant change to a manufacturing processes (e.g. sterilization site change, manufacturing site change), the Registered Manufacturing Site notifies the Marketing Authorization Holder so as the Marketing Authorization Holder can take appropriate regulatory actions [MHLW MO169: 29].</p> <p>Requirements implementation Verified and described within two audited samples: DEMF SC6500: Anlage A02 zu Dokumentation von Produktionsprozessen, 02, point 4. „Bewertung der Änderungen“ including question „Aktualisierung Process FMEA „ and „ Verification needed“ and Validierung erforderlich“ . Additional it is assured that if any change in STED of products is needed (change in PQ 2110), that the Design change process is applicable and respective reports will be done. Assessment of changes are triggered and the following SOP's and instructions have to be followed for decision about significant change and related duties: DWAG PQ2110 : Regulatory Approval to Market Product DWAG PQ2110 - en - 04.00 , Rev. 04.00 A08 DWAG PQ2110 Assessment of changes to medical devices, rev 04.00 – specifics of all MDSAP countries are inserted (Canada/Brazil/Japan/Australia/USA/Europe) and supported by change overview matrix with further country specifics of all MDSAP countries helping for the decision whether there is a significant change. If any significant change is evaluated a regulatory affairs manager will be informed for conduction of all further needed steps related to different MDSAP areas affected.</p> <p><u>MAI 8 – Identification and Control of Nonconforming Product (HD)</u> Manufacturer has established the process to assure controls are in place to ensure that product which does not conform to product requirements is identified, isolated and investigation is performed. The auditor has reviewed examples of communication and documentation and investigation of NC product – the examples are listed below in the key records.</p> <p><u>MAI 9 - Action Regarding Nonconforming Product Detected After Delivery (HD)</u></p>

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	<p>When a nonconforming product is detected after delivery or use the action is taken appropriate with the risk, or potential risks, of the nonconformity. The risk of the detected non-conformity is evaluated for the devices already delivered. Also, potential risks are evaluated.</p> <p><u>MAI 10 - Internal audit (HD)</u> Regular internal audits are conducted at planned intervals, all department/ processes have to be audited minimum once within 3 years (some each 2 years, some annually). The frequencies are defined in Internal Audit Covering document. If a critical deviation is found during the regular audit, an unannounced surveillance audit is also carried out. The audit triggers are defined. An internal audit includes to follow the internal audit procedure, internal audit plan, Protocol / Checklist MD and global internal audit summary report. The action / MNC or NC issued during the internal audit must be followed up. The NC/ MNC can be documented as documented action or as CAPA and are processed in Trackwise. There are 24 internal audits listed in Audit program 2022, 17 were performed, 4 were postponed due to the resource's issues. The rationale for postponed audit is documented. The KPI for internal audit are defined e.g.: complete 100 % of audit report within 14 days. The target has been reached with 89%.</p> <p>During the audit we check the last internal audit of PQ calibration process conducted in February 2023 and the Internal audit of BU Workplace Infrastructure. It could be shown that the customer adheres to his procedure and all required documents could be presented. The qualification of internal auditors is defined and documented, also the role of expert is considered. As an internal lead auditor, you have to have three years of experience as an auditor and depending on the standard / regulation you need at least three audits as an auditor. The manufacturer conducts annually auditor exchange/ training for authorized auditors.</p> <p><u>MAI 11 - Information Supplied for Management Review (MSz)</u> It could be determined that if relevant information regarding nonconforming product, quality management system nonconformities, corrections, corrective actions, and preventive actions has been supplied to management for management review. One-pager for management review includes and Handling complaints including Reporting to regulatory authorities. Reported to management review: - Number of Complaints, number of reportable complaints, - Number of Compentent Board meetings - Number of cases of death involving Dräger device - Complaint reliability rate (general + individually by BU) Trending for complaints vs prior years.</p> <p>For Field actions: Number of ongoing (56) and new (40) field action Total Number of new field actions Thereof FSCA (12) Thereof FQ Improvement actions (28) Number of ongoing field actions end of year (56) Overdue at the end of the year (28) Overdue >3 months (22) 2023 was an all time high for field actions.</p> <p><u>MAI 12 - Evaluation of Information from Post-Production Phase, Including Complaints (MSz)</u> Confirmed that the medical device organization has made effective arrangements for gaining experience from the post-production phase, including postmarket surveillance, handling complaints, and investigating the cause of nonconformities related to advisory notices with provision for feedback into the Measurement, Analysis and Improvement process. Verified that information from the analysis of production and post-production quality data was considered for amending the analysis of product risk, as appropriate. Records of complaints for review that represent the highest risk to the user or have the largest impact on the ability of the device to meet its essential design outputs have been selected. DCS PQ2010 describes Complaint handling (for all Dräger products, not only medical devices; however, process distinguishes between medical devices and non-medical devices). Input to Complaint Handling can come from any complaining person (internal or external). Respective Forms are available (Attachment A01). Trackwise is used to electronically handle complaint information, fed either by members of the Sales and Service organisations, or supervisory unit (PMS department Lübeck). Responsible legal manufacturer (Lübeck, China, India, USA, Dräger Safety UK + China) of product will be informed by PMS Department -all legal manufacturers work with trackwise. Legal Manufacturer decides if complaint is accepted and if it is marked as adverse event.</p> <p><u>MAI 13 - Communications with External Parties Involved on Complaints (MSz)</u> Where investigation determines that activities outside the medical device organization, contributed to a customer complaint, it could be verified that records show that relevant information was exchanged between the organizations involved. DCS PQ2010 Step 6 "Acknowledgement; request for additional information and/or return of material."</p> <p>Australia (TGA): DEMF PQ2000 : Post Market Surveillance System DEMF PQ2000 - en - 02.00 , Rev. 02.00</p> <p>Brazil (ANVISA): Complaint Procedures: DEMF PQ2010 : Complaint Handling DEMF - PQ2010 - en - 02.00 , Rev. 02.00</p>

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Subsystem	Measurement, Analysis, and Improvement - CAPA and Internal Audit
	<p>Canada (HC): Complaint and recall Procedures: DEMF PQ2010 : Complaint Handling DEMF - PQ2010 - en - 02.00 , Rev. 02.00 DEMF PQ2520 : Field Action (FA) DEMF PQ2520 - en - 05.00 , Rev. 05.00</p> <p>Japan (MHLW/PMDA) Complaint Procedures: DEMF PQ2010 : Complaint Handling DEMF - PQ2010 - en - 02.00 , Rev. 02.00</p> <p>United States (FDA): Complaint Procedures: DEMF PQ2010 : Complaint Handling DEMF - PQ2010 - en - 02.00 , Rev. 02.00</p> <p><u>MAI 14 - Evaluation of Complaints for Adverse Event Reporting (MSz)</u> Verified that the medical device organization has defined and documented procedures for the evaluation of complaints for adverse event reporting. It could be confirmed that decisions to not report complaints were made according to established procedures and a documented rationale.</p> <p><u>MAI 15 - Evaluation of Quality Problems for Advisory Notices (MSz)</u> Confirmed that decisions to not report complaints were made according to established procedures and a documented rationale. Records for review of quality problems that were evaluated for potential issuance of advisory notices (include records where a decision was made not to issue an advisory notice as well as records of decision to issue advisory notices) and assess whether the organization has taken actions appropriately based on risk and documented the rationale have been selected.</p> <p><u>MAI #16 Top Management Commitment to Measurement, Analysis, and Improvement Process (MSz)</u> Based on the assessment of the Measurement, Analysis and Improvement process overall, it could be determined that management provides the necessary commitment to detect and address product and quality management system nonconformities, and ensure the continued suitability and effectiveness of the quality management system.</p>
Reviewed documents and records (identification and revision)	<p><u>MAI 1 (GM)</u> DCGL/DCS PQ2510-013-en-00 SOP Corrective and Preventive Actions (BIC no new toll modulation) DEMF/DCS PQ2510 : Corrective and Preventive Actions - en - , Rev. 00.01 (BIC no new tool modulation) DEMF PQ3300 System related Corrective and Preventive actions revision 4.00 20. 06 2022 CAPA trigger& criteria PQ3300 – A01 2022-06-20 revision 04.00 PQ3300 – A02 Risk evaluation template, RI 02.00 DEMF SC6110 : Behandlung von Abweichungen in der Produktion DEMF - SC6110 - de - 00.00 , Rev. 00.00 DEMF SC6111 : Lenkung von fehlerhaftem Material DEMF - SC6111 - de - 00.01 , Rev. 00.01 Management Review 2022 – DWAG 2022-03-22, signed by Stefanie Hirsch and Mr. Schrofner One pager MR input 2023: Example One Pager – Handling of CAPA's: Product CAPA 22 CAPA's closed on 2022, risk in time completion 98% System CAPA: CAPA plan closing within 30 days (68% reached) CAPA completed until target due date (only 48%)-> actions defined on CAPA plan Action list status 18.09 2023 Handlings CAPA a) provision of timely CAPA handling last result positive trend of system CAPA handling, 15.09.2023</p> <p><u>MAI 1 (HD)</u> DCS PQ2510-013-en-00.01 SOP Corrective and Preventive Actions. Rev. 00.01. 03.09.2020 DEMF PQ2510 A01 en 00.02 CAPA Criteria CAPA decision template, revision 2 DWAG - CAPA Monthly Report 2023-08 PR ID 121799 Product CAPA report - BU HCA PKG 2022-003059 dd 2022-12-12</p> <p><u>MAI 2 (GM)</u> DEMF PQ8050 : Statistical Techniques - en_de - 00.00 , Rev. 00.00 , including tool-boxes for concrete statistical methods. It s required that in every SOP it should be evaluated whether statistical method is needed and that the appropriate method should be chosen by proses autor and reviewer Management Review 2022 – DWAG 2022-03-22, signed by Stefanie Hirsch and Mr. Schrofner One pager MR input 2023: Example One Pager Product feedback, general in target (I all feedback will be evaluated not limited to complaints) Example One Pager Risk management: action Item resources Example One pager Product compliance Example One Pager complaints, yellow: slightly negative trend regarding backlog and timely closing; Quality project: process redesign (channel one) Example Handling of field action: 40 new opened, total 48- actions defined because of big backlog Example One Pager Handling of Design changes: view on long-term processing changes Example One Pager performance Sourcing: e.g. supplier audits, Supplier PPM slightly above target (e.g. supplier for accessories) Example One Pager Performance of distribution: all topics on track Example One Pager Performance of Service: all topics on track Example One Pager internal and external audit: all topics on track</p> <p><u>MAI 2 (HD)</u></p>

Subsystem	Measurement, Analysis, and Improvement - CAPA and Internal Audit
	<p>DCS PQ2510-013-en-00.01 SOP Corrective and Preventive Actions. Rev. 00.01. 03.09.2020 CAPA decision sheet 2023_Q2 Humidification</p> <p><u>MAI 3 (GM)</u> #122371/#122373/#122374/#122377/#122378-> all audited cases have root cause analysis One case audited deeper with related 5 WHY analysis: Audit 19.09.2023 #122373 (documented action) Re-open Product CAPA PR96387 and update 3D5Why - complete Root Cause analysis and derive necessary (corrective) actions if applicable product "Babyleo" TN500 unacceptable pollution degree- root analysis reopened and updated under usage of 5 Why- root cause result: mistakenly not identified as "complex component". 5 Why template updated,30.06.2023.</p> <p>#103501 production and process controls, rework not documented on process. Risk evaluation, no risk for product/user/patient/employees/environment but a risk for IMS PQ3300 – A02 Risk evaluation template to #103501 risk for IMS documented but accepted because only IMS and not product patient user or environment affected.</p> <p>#117431 CAPA timelines, overdue. Risk evaluation, no risk for product/user/patient/employees/environment but a risk for IMS PQ3300 – A02 Risk evaluation template to #117431 risk for IMS documented certification endangers certification_actions are defined -> see action list under MAI 1</p> <p><u>MAI 3/4 (HD)</u> DCS PQ 2010 de 013 -02.00 Complain Handling 2020-03-01. DSC SC 5220 Handling of supplier nonconformance reports for field materials. DWAG IN4230 design changes revision 5.0 dd. 30.06.2023 DCS PQ 2030 The letter to customer DCS PQ 2010 A05 Investigation report on the complaint DCS PQ 2010 A07 revision 13 List of criteria for examinations PR 124066 – Brazil Email Fa. GPE dd 09.12.2022 PR 124066 dd. 03.11.2022 PR 1321136 dd. 21.06.2023 PR 126323 dd. 06.12.2022 PR 126748 dd. 08.12.2022 DCR 2023 – 004142 DCR 2023 000515 DCR 2023-001245</p> <p><u>MAI 4 / MAI 5 (GM)</u> 1/2DR -000069 Prozess-FMEA PIA-PIA2_00, 18.10.2022 (0 revision because of usage of a new FMEA tool)- underlying sources of identified risks have been evaluated and documented</p> <p>Management Review 2022 – DWAG 2022-03-22, signed by Stefanie Hirsch and Mr. Schrofner Onepager MR input 2023: Example One Pager: internal audit results: findings will be analysed acc. to relation to all relevant processes. Observed unusual amount of findings in a process will be used as indicator to define some preventive action in the related area. An evaluation will be done at each MR and an overall result documented on page "evaluation Internal Audits" -> data related to One pager- 2023 result no unexpected accumulation of mayors</p> <p>Example One Pager – Handling of CAPA's: Product CAPA 22 CAPA's closed on 2022, risk in time completion 98% System CAPA: CAPA plan closing within 30 days (68% reached) CAPA completed until target due date (only 48%)- > actions defined on CAPA plan Action list status 18.09 2023 Handlings CAPA a) provision of timely CAPA handling last result positive trend of system CAPA handling, 15.09.2023</p> <p>#103501 production and process controls, rework not documented on process. Risk evaluation, no risk for product/user/patient/employees/environment but a risk for IMS PQ3300 – A02 Risk evaluation template to #103501 risk for IMS documented but accepted because only IMS and not product patient user or environment affected.</p> <p>#117431 CAPA timelines, overdue. Risk evaluation, no risk for product/user/patient/employees/environment but a risk for IMS PQ3300 – A02 Risk evaluation template to #117431 risk for IMS documented certification endangers certification_actions are defined -> see action list under MAI 1</p> <p><u>MAI 5 (HD)</u> DCS PQ2510-013-en-00.01 SOP Corrective and Preventive Actions. Rev. 00.01. 03.09.2020 DEMF PQ2510 A01 en 00.02 CAPA Criteria CAPA decision template, revision 2 DWAG - CAPA Monthly Report 2023-08 PR ID 121799 Product CAPA report - BU HCA PKG 2022-003059 CAPA PR ID 118754</p>

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	<p>PKG 2022-002059 PR 127593- _ Rerecords for effectiveness check PR 127593_ FQA Warranty evaluation 2023-09-06 DCR 2022-004758</p> <p><u>MAI 6 (HD)</u> DWAG IN4230 design changes revision 5.0 dd. 30.06.2023 PR 1321136 dd. 21.06.2023 PR 126748 dd. 08.12.2022 DCR 2023 - 004142 DCR 2023-001245 Project EHF Verification Summary report 06.03.2023 SAP Stammdaten ZM90 version 11 DCR 2021-006406 PKG 2020-002624 EHF Complain record BU HCA 01.09.2022-13.09.2023 SAP Case Management PSB/CFT330 PPM Accessories</p> <p><u>MAI 7 (GM)</u> DEMF SC6500: Anlage A02 ATLAN Arbeitsplatz SM2 SM1, change of work step have been transferred from 2 to 1, Vorgang 0030, step enhanced and transferred to Vorgang 0040 (Typenschildanbringung component), signed 23.08.2023 (two eyes principle-> no significant change, no validation needed, no change in process FMEA, no training needed, DEMF SC6500: Anlage A02 Babyleo Arbeitsplatz SM2 SM1, change of work step have been transferred from Vorgang 0500 to Vorgang 0400, step enhanced and transferred to Vorgang 0040 no new steps, signed 03.02.2023 (two eyes principle-> no significant change, no validation needed, no change in process FMEA, no training needed. DEMF SC6500: Anlage A02 zu Dokumentation von Produktionsprozessen, 02, point 4. „Bewertung der Änderungen“ including question „Aktualisierung Process FMEA „ and „Verification needed“ and Validierung erforderlich“ . Additionally, it is assured that if any change in STED of products is needed (change in PQ 2110), that the Design change process is applicable and respective reports will be done. Assessment of changes are triggered and the following SOP's and instructions have to be followed for decision about significant change and related duties. DWAG PQ2110 : Regulatory Approval to Market Product DWAG PQ2110 - en - 04.00 , Rev. 04.00 A08 DWAG PQ2110 Assessment of changes to medical devices, rev 04.00 – specifics of all MDSAP countries are inserted (Canada/Brazil/Japan/Australia/USA/Europe) and supported by change overview matrix with further country specifics of all MDSAP countries helping for the decision whether there is a significant change. If any significant change is evaluated a regulatory affairs manager will be informed for conduction of all further needed steps related to different MDSAP areas affected</p> <p>DEMF SC6500 : Dokumentation von Produktionsprozessen DEMF SC6500 - de - 00 , Rev. 0 DEMF SC6500: Anlage A02 zu Dokumentation von Produktionsprozessen, 02, point 4. „Bewertung der Änderungen“ including question „Aktualisierung Process FMEA „ and „Verification needed“ and Validierung erforderlich“ . Additional it is assured that any change in STED of products is needed (change in PQ 2110), that the Design change process is applicable and respective reports will be done. DWAG PQ2110 : Regulatory Approval to Market Product DWAG PQ2110 - en - 04.00 , Rev. 04.00 A08 DWAG PQ2110 Assessment of changes to medical devices, rev 04.00</p> <p><u>MAI 8 (HD)</u> DCS PQ 2030 The letter to customer Email Fa. GPE dd 09.12.2022</p> <p><u>MAI 9 (HD)</u> CAPA PR 121799 Risk Management Hazard Analysis Nova & classical Star NIV Masks. 2023. 01.30</p> <p><u>MAI 10 (HD)</u> DEMF PQ3210-013-en-06.00 Internal Audits 01-05-2023 DEMF PQ3210 _ A99 Requirements for internal Auditors Management Review 30.03.2023 including action list. Annual Auditors Exchange & Training - Dräger Lübeck 2023-02-17 Internal Audit program 2022 revision 03, Feb 7, 2023. Internal Audit program 2023 Rev 02 signed on July 24, 2023. DWAG IMS – Audit 2023 QRA PQ Calibration (#115859) Audit Agenda DWAG IMS 2023 QRA PQ _ PR 127001 rev01 20230220 Audit report PR#114859 signed 27-02-2023. Internal Audit Covering 2023-2025 rev 00 signed Feb 7, 2023 List of internal auditors 2023-07-19 as per PQ 3210 Bildungslebenslauf Auditor Dr. LN 2023-09-06 Internal Audit Report PR# 115861 BU Workplace Infrastructure</p> <p><u>MAI 11 - 16 (MSz)</u> One Pager für Management review, 2023-03-31, Page 39+40 All Records kept in Trackwise complaint system DCS PQ2010 Step 7: "Reporting Requirements applicable?" DCS PQ2010 Step 6 "Acknowledgement; request for additional information and/or return of material." DEMF PQ2000 : Post Market Surveillance System DEMF PQ2000 - en - 02.00 , Rev. 02.00 DEMF PQ2010 : Complaint Handling DEMF - PQ2010 - en - 02.00 , Rev. 02.00</p>

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	DEMF PQ2520 : Field Action (FA) DEMF PQ2520 - en - 05.00 , Rev. 05.00 MDR: There are processes in place for CAPA and Post-Production Phase, Including Complaints (see above)
Names and titles of persons interviewed	Ulf Hagedorn-Head of IMS Audit Management Ralf Kornmann -Product Manager Therapie Wasner, Carsten -Cyber security Engineer Other participants including roles will be provided by Ulf Hagedorn Both Stephan - Quality System manager Quality & Regulatory Affairs
Products, components, or projects reviewed	DEMF SC6500 DWAG PQ2110 #103501 production and process controls #117431 CAPA timelines 2DR -000069 Prozess-FMEA CAPA`s #122371/#122373/#122374/#122377/#122378 Management Review 2022 – DWAG 2022-03-22
Statement concerning conformity based on objective evidence reviewed for this subsystem	This process is effectively implemented and conforms with requirements

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2.5.4 Device Adverse Events and Advisory Notices Reporting, PMS and Vigilance

Subsystem	Device Adverse Events and Advisory Notices Reporting Post-Market Surveillance and Vigilance
Audit trail records of	Martin Szepepannek
Area(s) visited (location, e.g., site visited)	Location # 1 For more details related to Audit location and time refer to chapter 2.2 of this report.
Audit criteria according to audit plan	"Medical Device Adverse Events and Advisory Notices Reporting: Notification of Adverse Events (MDSAP Chapter 4, Task 1, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 7.2.3, 8.2.2, 8.2.3 + (DIN)(EN) ISO 9001 - 7.5.1, 8.2.1, 8.5.5, 9.1.2 + MDSAP - Australia - As required by MDSAP AU P0002 + MDSAP - Brazil - As required by MDSAP AU P0002 + MDSAP - Canada - As required by MDSAP AU P0002 + MDSAP - Japan - As required by MDSAP AU P0002 + MDSAP - USA - As required by MDSAP AU P0002 + MDR - Article 10.9 ¶3(k), 10.12, 10.13; Article 80, 87, 88, 89, 94 + MDD - Article 10" "Medical Device Adverse Events and Advisory Notices Reporting: Notification of Advisory Notices (MDSAP Chapter 4, Task 2, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 7.2.3, 8.2.3, 8.3.3 + (DIN)(EN) ISO 9001 - 7.5.1, 8.2.1, 8.5.5, 8.7 + MDSAP - Australia - As required by MDSAP AU P0002 + MDSAP - Brazil - As required by MDSAP AU P0002 + MDSAP - Canada - As required by MDSAP AU P0002 + MDSAP - Japan - As required by MDSAP AU P0002 + MDSAP - USA - As required by MDSAP AU P0002 + MDR - Article 10.9 ¶3 (k), 10.12, 10.13; Article 80, 87, 88, 89, 94 + MDD - Article 10"
Brief description of processes or activities evaluated to demonstrate what was audited related to the listed key QMS documents and records reviewed below considering inputs, outputs, and measures	MDAER #1 Notification of Adverse Events (Msz) Verified that the medical device organization has a process in place for identifying devicerelated events that may meet reporting criteria as defined by participating regulatory authorities. Verified that the complaint process has a mechanism for reviewing each complaint to determine if a report to a regulatory authority is required. Confirmed that the medical device organization's processes meet the timeframes required by each regulatory authority where the product is marketed. DCS PQ2010 A02_Rev-03.00 Decision Tree for Medical device Reporting This Tree is used to retrieve informaton on reporting timelines and countries to report. 30 countris + EU is listed. 17 MA, 2 Feldaktionen Samples taken: PR#121742 Doctors Hospital Augusta Infinity ACS Workstation CC (V500/C500) Stopped providing breaths and registered data failure Date of Registration in Trackwise 2022-09-08 - reportable Complaint Closure Report 121742 Date of Event: 2022-08-17 Complaint accepted 2022-08-17 Root Cause: printed Circuit Board failure Decision: 2022-09-19 - Reportable due to Death/Serious Injury possible, in case bretahing pressure drops to ambient, and therefore deterioration of heathl can not be excluded. Countries to report: USA, China, Malaysia 122106_MDR.pdf Trackwise Manufacturer Report 9611500-2022-00241 Final Report 9611500-2022-00241 Follow-Up #1 PR#131186 Bana University medical center Phoenix Perseus A500 "Vent fail" Trackwise entry 2023-06-14 - reportable Complaint Closure Report 131186 Date of Event: 2023-06-12 Complaint accepted: 2023-06-14 Case Reported 2023-06-28 Root Cause: coul not be tracked down to device failiure (external leakage) Decision: 2023-06-28, reportable due to not excludeable device failure Countries to report: USA; China, Malaysia MDR_Initial_Report_PR131186.pdf Trackwise Manufacturer Report 9611500-2023-00236 Final Report 2023-08-08 9611500-2023-00236 Follow-Up #1 PR#121766 Maxima Medisch Centrum Babyleo TN500 "Matress Failure during use" Trackwise entry 2022-09-09 – non-reportable Complaint Closure Report 121766 Date of Event: 2022-08-09 Complaint accepted Root Cause: misplaced NTC sensors during Production of matress Decision: 2023-05-04 PR#121670 Martini Ziekenhuis Babyleo TN500 „Overflow of Humidifier and onto mother`s leg" Entry 2022-09-07 – non reportable Complaint Closure Report 121670 Date of Event 2021-06-24 Complaint accepted 2022-09-07 Root Cause: narrowed opening of a nozzle Decision: non-reportable 2022-09-14 FSCA-Case: PR#116051 Klinikum Ludwigsburg Polaris Multimedia "Ausleger mit Federarm und Monitor während laufender OP abgestürzt" - reportable Complaint Closure Report Date of Event: 2022-02-22 Complaint accepted: 2022-03-15 Case Reported: 2022-03-01 Root Cause: faulty Dräger installation instructions and accordingly wrong installation

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Subsystem	Device Adverse Events and Advisory Notices Reporting Post-Market Surveillance and Vigilance
	<p>Decision: 2022-03-16 Countries to report: EU incl. CH, UK (□ DE) , USA MIR MDV Initial Report PR116051.pdf form 2022-03-15 Trackwise Manufacturer Report FSCA Dräger Ref 123143 MIR Final Report PR116051 BfARm ref 06223/22 from 2022-11-08 Competent Board Meeting Minutes 2022-09-30 for Meeting 2022-08-22, including documented evidence for decision to do FSCA eMail 2022-10-30 to Dräger QR responsible Personens of the countries QRA Network Letter Display Holder 2022-10-30 Safety Notice EN.pdf from October 2022 Reply and Order card_EN</p> <p>Competent Board Process describes the procedure for carrying out Competent Board meetings; theses take place in cases to evaluate a poetentially serious product risk, and decide on necessary measures to mitigate the potentially serious product risk. Competent Board responsibility is delegated by Top Management to appointed management employees of interdisciplinary areas. Competent Board meetings are decision meetings.</p> <p>Australia (TGA): DEMF PQ2000 : Post Market Surveillance System DEMF PQ2000 - en - 02.00 , Rev. 02.00</p> <p>Brazil (ANVISA): Complaint Procedures: DEMF PQ2010 : Complaint Handling DEMF - PQ2010 - en - 02.00 , Rev. 02.00</p> <p>Canada (HC): Complaint and recall Procedures: DEMF PQ2010 : Complaint Handling DEMF - PQ2010 - en - 02.00 , Rev. 02.00 DEMF PQ2520 : Field Action (FA) DEMF PQ2520 - en - 05.00 , Rev. 05.00</p> <p>Japan (MHLW/PMDA) Complaint Procedures: DEMF PQ2010 : Complaint Handling DEMF - PQ2010 - en - 02.00 , Rev. 02.00</p> <p>United States (FDA): Complaint Procedures: DEMF PQ2010 : Complaint Handling DEMF - PQ2010 - en - 02.00 , Rev. 02.00</p> <p><u>MDAER #2 Notification of Advisory Notices (Msz)</u> Verified that advisory notices are reported to regulatory authorities when necessary and comply with the timeframes and recordkeeping requirements established by participating regulatory authorities. CRT Action Item Dräger FSCA ICM PR126573, TPS ID VM63012: "The investigation confirmed that when ICM is used in combination with a syringe pump connection, under certain under certain conditions, ICM may show entries in the daily curve that were not deliberately created by the user. These entries cannot be edited or deleted by the user. If these additional entries unnoticed, this can lead to inaccurate documentation of prescriptions or previous treatment in the program. program and thus potentially lead to incorrect treatment decisions." Action Item: "Since the Cause of the behaviour has been identified, please review the rationale for not updating the affected systems, considering the principle of integrated safety". During audit, manufacturer provided updated information on that case and behavior. This behavior has been changed in the next regular release of the Software (V14) and in Bugfix Version (V 13.02, released 07/2023). Therefore the requested rationale is not needed anymore. The Bugfix Version will be rolled out with a new Field action (see "Decision and Order") Background Information (as communicated to BFARM 2023-08-08): ICM is used by customers in 5 different Software Versions (V9-V13). Bug fixing was available with V13.02 (available since 07/2023) and V14. Installation of V12 + V13 are technically updateable to 13.02; however, this involves a high effort withing hospitals, since the IT infrastructure is involved; therefore, Dräger forecasts this update to take around 12 months time. The problem described within FSCA can only happen in installations that use the option "Syringe Pumps Connection"; this connection is only be used by very few customers. Dräger will approach customers with these versions in order to either update to V13.02 or to deactivate the option causing the issue.</p> <p>Records for this case: Competent Board Decision 2023-01-13 Specific Risk Assessment RM CAPA PR123704-signed.pdf TSB_4_ICM_Decision and Order_signed.pdf 2023-08-01 „13.02 ist verfügbar“ Release Notes ICM Patientenmanagement Software 13.02 6495.525_de, versendet 2023-07-28 Kundeninformationsschreiben im Entwurf vorhanden (...), wird noch im September versendet. eMail 2023-08-08 to Competent Authority Landesamt für soziale Dienste Schleswig-Holstein PR123101 Decision Closure Report 2023-09-19 Jira-Defect Entry Ticket ICM-13149 Jira-Defect Entry Ticket ICM-13254 – for V13.02 – 1306887 Test case 13254: Approved, Passed RQM Test case 114863 SW-release-No mt-1622 Prt-No. MK0517103 for V13.02 ICM Customer letter Fluid Management Deutsch update _final.pdf (2023-09)</p>

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Subsystem	Device Adverse Events and Advisory Notices Reporting Post-Market Surveillance and Vigilance
	<p>Australia (TGA): DEMF PQ2000 : Post Market Surveillance System DEMF PQ2000 - en - 02.00 , Rev. 02.00</p> <p>Brazil (ANVISA): Complaint Procedures: DEMF PQ2010 : Complaint Handling DEMF - PQ2010 - en - 02.00 , Rev. 02.00</p> <p>Canada (HC): Complaint and recall Procedures: DEMF PQ2010 : Complaint Handling DEMF - PQ2010 - en - 02.00 , Rev. 02.00 DEMF PQ2520 : Field Action (FA) DEMF PQ2520 - en - 05.00 , Rev. 05.00</p> <p>Japan (MHLW/PMDA) Complaint Procedures: DEMF PQ2010 : Complaint Handling DEMF - PQ2010 - en - 02.00 , Rev. 02.00</p> <p>United States (FDA): Complaint Procedures: DEMF PQ2010 : Complaint Handling DEMF - PQ2010 - en - 02.00 , Rev. 02.00</p> <p>MDR: Vigilance reporting and analysis DEMF PQ2000 : Post Market Surveillance System DEMF PQ2000 - en - 02.00 , Rev. 02.00 DWAG IN4250 : Clinical Evaluation DWAG IN4250 - en - 04.00 , Rev. 04.00 Trend Reporting is described in Attachment 04 of PQ2000 (general trending and trend reporting in accordance with article 88)</p> <p>MDR The importer undertakes to notify TÜV SÜD PS without delay of the non-compliance and of any corrective action taken where the device with identification number CE 0123 presents a serious risk or in the course of the post-market surveillance, a need for preventive or corrective action or both is identified</p>
Reviewed documents and records (identification and revision)	<p>DEMF PQ2000 : Post Market Surveillance System DEMF PQ2000 - en - 02.00 , Rev. 02.00 DEMF PQ2010 : Complaint Handling DEMF - PQ2010 - en - 02.00 , Rev. 02.00 DCS PQ2030: Complaint Handling in Sales and Service, Rev. 06.00 DCS PQ 2020: Competent Board Rev. 01 DEMF PQ2020 Competent Board_A01-en-02.00 Rev. 02:00 DEMF PQ2520 : Field Action (FA) DEMF PQ2520 - en - 05.00 , Rev. 05.00 DWAG PQ2011 : Screening of Repair and Service Notifications DWAG - PQ2011 - en - 00.00 , Rev. 00.00</p> <p>Records: PSUR Babyleo PSUR Perseus A500 11249101 rev. 00 Axxx family, covering 2022-01-01 to 2022-12-31 Includes internal data sources: Incidents (Perseus 384), serious incidents without harm (25) Inputs are generated by referenced documents - Post Production Information report PPI_ECRI_2022 Rev.00 from 2022-03-30 - PMCF Plan 101-12 MDR Perseus A500 2022-03-25 - PMCF Plan atlan 2022-07-04 - Axxx_PMS_Plan 2022-04-02 11100333 Rev. 00 Axxx PMS Plan PMS Plan Babyleo (Thermoregulation) 2023-06-11 PMS Report Babyleo (Thermoregulation) 2023-08-01 Number of Vigilance reports FDA – Trackwise Export 2023-09-13, including 416 reportable Events to FDA. Number of Complaints worldwide – Trackwise Export 2023-09-13, including 4311 complaints in general Vigilance Contact List (updated 2023-07-21) includes contact data of each potentially involved organisation</p>
Names and titles of persons interviewed	<p>Sonja Hillmer (Head of Post Market Surveillance) Sven Mamerow (Post Market Surveillance Manager) Dorothee Neitzel (scribe) (Post Market Surveillance Manager) Christine Rafalzik (scribe) (Post Market Surveillance)</p>
Products, components, or projects reviewed	<p>Babyleo Perseus A500</p>
Statement concerning conformity based on objective evidence reviewed for this subsystem	<p><input checked="" type="checkbox"/> This process is effectively implemented and conforms to requirements. <input type="checkbox"/> Actions are needed for this process to conform to requirements. See audit finding list.</p>

2.5.5 Design and Development

Subsystem	Design and Development
Audit trail records of	Martin Szepeannek / George Pavlov / Gabriele Mousset / Honorata Donnermair / Melanie Gaßen
Area(s) visited (location, e.g., site visited)	Location # 10578 For more details related to audit location and time refer to chapter 2.2 of this report.
Audit criteria according to audit plan	<p>"Design and Development: Identification of Devices Subject to Design and Development Procedures; Technical Documentation (MDSAP Chapter 5, Task 1, Site: 10578); (DIN)(EN) ISO 13485 - 4.1.1, 4.2.1, 7.1, 7.3.10 + (DIN)(EN) ISO 9001 - 4.4, 7.5.1, 7.5.3, 8.1, 8.4 + MDSAP - Australia - TG(MR)R Schedule 3, Part1, (excluding or including clause 1.6) + MDSAP - Brazil - RDC ANVISA 16/2013: 4.1.7, 4.2 + MDSAP - Canada - CMDR 9, 10 to 20 + MDSAP - Japan - MO169: 5-1, 6, 26, 36-2; [Old: 5, 6, 26] + MDSAP - USA - 21 CFR 820.30(a) + MDR - Article 10.1, 10.2, 10.9 ¶3 (e, g); Annex IX 2.2 ¶2 (c2) + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>Design and Development: Selection of a Completed Design and Development Project (MDSAP Chapter 5, Task 2, Site: 10578)</p> <p>"Design and Development: Design and Development Planning (MDSAP Chapter 5, Task 3, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 7.1, 7.3.2 + (DIN)(EN) ISO 9001 - 7.5.1, 8.1, 8.3.2 + MDSAP - Australia - TG(MD)R Sch3 P1 Cl 1.4(4)&(5)(c) + MDSAP - Brazil - RDC ANVISA 16/2013: 4.1.2, 4.1.11 + MDSAP - Canada - CMDR 32 + MDSAP - Japan - MO169: 6, 26, 30 + MDSAP - USA - 21 CFR 820.30(b), 820.30(j) + MDR - Article 10.9 ¶3 (g) + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>"Design and Development: Implementation of the Design and Development Process (MDSAP Chapter 5, Task 4, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 7.3.10 + (DIN)(EN) ISO 9001 - 7.5.1, 7.5.3, 8.3.1 + MDSAP - Australia - TG(MD)R Sch3 P1 Cl 1.4(4)&(5)(c) + MDSAP - Brazil - RDC ANVISA 16/2013: 4.1.1 + MDSAP - Japan - MO169: 6, 30, 36-2; [Old: 6, 30] + MDSAP - USA - 21 CFR 820.30(a), 820.30(c), 820.30(j) + MDR - Article 10.9 ¶3 (g) + MDD - Annex II (3.2)"</p> <p>"Design and Development: Design and Development Input (MDSAP Chapter 5, Task 5, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 5.2, 7.2.1, 7.3.3, 8.2.1 + (DIN)(EN) ISO 9001 - 5.1.2, 7.5.1, 8.2.2, 8.3.3, 8.5.5, 9.1.2 + MDSAP - Australia - TG(MD)R Sch1 P1 2, Sch3 P1 Cl 1.4(2)&(5)(c), Sch 3 P1 1.4(3)(a)&(b) + MDSAP - Brazil - RDC ANVISA 16/2013: 2.4, 4.1.3, 4.1.11 + MDSAP - Canada - CMDR 10-20, 21-23, 66, 67, 68 + MDSAP - Japan - MO169: 6, 11, 27, 31, 55-1; [Old: 6, 11, 27, 31, 55] + MDSAP - USA - 21 CFR 820.30(c), 820.30(g) + MDR - Article 10.9 ¶1 s2, 10.9 ¶3 (b), 10.11; Annex IX 2.2 ¶2 (c2, c6, c8); Article 1 (3), Article 1 (4, 6, 7, 8, 9), Article 2 (1) + MDD - Annex II (3.2)"</p> <p>"Design and Development: Completeness, Coherence, and Unambiguity of Design and Development Input (MDSAP Chapter 5, Task 6, Site: 10578); (DIN)(EN) ISO 13485 - 7.3.3 + (DIN)(EN) ISO 9001 - 8.3.3 + MDSAP - Australia - As required by MDSAP AU P0002 + MDSAP - Brazil - RDC ANVISA 16/2013: 4.1.3 + MDSAP - Japan - MO169: 31 + MDSAP - USA - 21 CFR 820.30(c)"</p> <p>"Design and Development: Design and Development Output and Design Verification (MDSAP Chapter 5, Task 7, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 4.2.3, 7.3.4 + (DIN)(EN) ISO 9001 - 7.5.1, 8.3.5 + MDSAP - Australia - TG(MD)R Sch3 P1 Cl 1.4(5)(c) + MDSAP - Brazil - RDC ANVISA 16/2013: 4.1.5, 4.1.4, 4.1.11 + MDSAP - Japan - MO169: 6, 7-2, 32; [Old: 6, 32] + MDSAP - USA - 21 CFR 820.30(d), 820.30(f) + MDR - Article 10.9 ¶3 (b); Annex IX 2.2 ¶2 (c5) + MDD - Annex II (3.2)"</p> <p>"Design and Development: Risk Management Activities Applied Throughout the Design and Development Project (MDSAP Chapter 5, Task 8, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 7.1, 7.3.3, 7.3.4 + (DIN)(EN) ISO 9001 - 7.5.1, 8.1, 8.3.3, 8.3.5 + MDSAP - Australia - TG(MD)R Sch1 P1 2, Sch3 P1 Cl 1.4(5)(c)(iii) + MDSAP - Brazil - RDC ANVISA 16/2013: 2.4, 4.1.11, RDC ANVISA 56/2001 + MDSAP - Canada - CMDR 10, 11, 15, 16 + MDSAP - Japan - MO169: 6, 26, 31, 32 + MDSAP - USA - 21 CFR 820.30(g) + MDR - Article 10.9 ¶3 (e) + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>"Design and Development: Design Verification or Design Validation to Confirm Effectiveness of Risk Control Measures (MDSAP Chapter 5, Task 9, Site: 10578); (DIN)(EN) ISO 13485 - 7.1, 7.3.6, 7.3.7 + (DIN)(EN) ISO 9001 - 8.1, 8.3.4 + MDSAP - Australia - TG(MD)R Sch1 P1 2, Sch3 P1 Cl 1.4(5)(c) + MDSAP - Brazil - RDC ANVISA 16/2013: 2.4, 4.1.4, 4.1.8, 4.1.11 + MDSAP - Canada - CMDR 10, 11, 15, 16 + MDSAP - Japan - MO169: 26, 34, 35-1, [Old: 26, 34, 35] + MDSAP - USA - 21 CFR 820.30(f), 820.30(g) + MDR - Annex IX 2.2 ¶2 (c5) + MDD - Annex II (3.2)"</p> <p>"Design and Development: Design Validation (MDSAP Chapter 5, Task 10, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 7.3.7 + (DIN)(EN) ISO 9001 - 7.5.1, 8.3.4 + MDSAP - Australia - TG(MD)R Sch1 P1 2; Sch3 P1 Cl 1.4(5)(d) + MDSAP - Brazil - RDC ANVISA 16/2013: 2.4, 4.1.8, 4.1.11 + MDSAP - Canada - CMDR 12, 18, 19 + MDSAP - Japan - MO169: 6, 35-1; [6, 35] + MDSAP - USA - 21 CFR 820.30(g) + MDR - Article 10.3, 10.9 ¶3 (f); Annex IX 2.2 ¶2 (c5); Annex XIV, Article 61, and Annex XIV part A + MDD - Annex II (3.2)"</p> <p>"Design and Development: Clinical Evaluation and/or Evaluation of Medical Device Safety and Performance (MDSAP Chapter 5, Task 11, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 7.3.7 + (DIN)(EN) ISO 9001 - 7.5.1, 8.3.4 + MDSAP - Australia - TG(MD)R Reg 3.11, Sch1 EP14, Sch3 P1 Cl 1.4(5)(c)(vii), Sch3 P8 + MDSAP - Brazil - RDC ANVISA 16/2013: 4.1.8, 4.1.11, RDC ANVISA 56/2001 + MDSAP - Canada - CMDR 12, 18, 19 + MDSAP - Japan - MO169: 6, 35-1; [Old: 6, 35] + MDSAP - USA - 21 CFR 820.30(g) + MDR - Article 10.3, 10.9 ¶3 (f); Annex IX 2.2 ¶2 (c5); Annex XIV, Article 61, and Annex XIV part A + MDD - Annex II (3.2)"</p> <p>"Design and Development: Software Design and Development (MDSAP Chapter 5, Task 12, Site: 10578); (DIN)(EN) ISO 13485 - 7.3.2, 7.3.10 + (DIN)(EN) ISO 9001 - 7.5.3, 8.3.2 + MDSAP - Australia - TG(MD)R Sch1 P1 2, Sch1 EP12.1 + MDSAP - Brazil - RDC ANVISA 16/2013: 2.4, 4.1.8, 4.1.11 + MDSAP - Canada - CMDR 20 + MDSAP - Japan - MO169: 30, 36-2; [Old: 30] + MDSAP - USA - 21 CFR 820.30(g) + MDR - Article 10.9 ¶3 (g) + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>"Design and Development: Design and Development Change (MDSAP Chapter 5, Task 13, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 4.2.3, 7.1, 7.3.9, 7.3.10, 8.2.1 + (DIN)(EN) ISO 9001 - 7.5.1, 7.5.3, 8.1, 8.3.6, 8.5.5, 8.5.6, 9.1.2 + MDSAP - Australia - As required by MDSAP AU P0002 + MDSAP - Brazil - RDC ANVISA 16/2013: 2.4, 4.1.4, 4.1.8, 4.1.10, 4.1.11, Brazilian Law 6360/76 - Art. 13 + MDSAP - Canada - CMDR 1, 34 + MDSAP - Japan - As required by MDSAP AU P0002 + MDSAP - USA - 21 CFR 820.30(i), 807 + MDR - Article 10.9 ¶1 s2, 10.9 ¶3 (a); Annex IX 2.2 ¶2 (c1, c8); Article 8, Article 9 + MDD - Annex II (3.2)"</p> <p>"Design and Development: Design Review (MDSAP Chapter 5, Task 14, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 7.3.2, 7.3.5 + (DIN)(EN) ISO 9001 - 7.5.1, 8.3.2, 8.3.4 + MDSAP - Australia - TG(MD)R Sch3 P1 Cl 1.4(5)(c)(i) + MDSAP - Brazil - RDC ANVISA 16/2013: 4.1.6, 4.1.11 + MDSAP - Japan - MO169: 6, 30, 33 + MDSAP - USA - 21 CFR 820.30(e) + MDR - Article 10.9 ¶3 (b); Annex IX 2.2 ¶2 (b2); Annex XI 6.2 ¶2 + MDD - Annex II (3.2)"</p> <p>"Design and Development: Impact Review of Design and Development Changes on Previously Made and Distributed Devices (MDSAP Chapter 5, Task 15, Site: 10578); (DIN)(EN) ISO 13485 - 7.3.9 + (DIN)(EN) ISO 9001 - 8.3.6, 8.5.6 + MDSAP - Brazil - RDC ANVISA 16/2013: 4.1.10 + MDSAP - Japan - MO169: 36-1; [Old: 36] + MDSAP - USA - 21 CFR 820.30(i) + MDR - Article 10.9 ¶1 s2, 10.9 ¶3 (a); Annex IX 2.2 ¶2 (c1, c8); Article 8, Article 9 + MDD - Annex II (3.2)"</p> <p>"Design and Development: Design Transfer (MDSAP Chapter 5, Task 16, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 4.2.3, 7.3.8 + (DIN)(EN) ISO 9001 - 7.5.1, 8.3.4 + MDSAP - Brazil - RDC ANVISA 16/2013: 4.1.7, 4.1.9, 4.1.11, 4.2 + MDSAP - Japan - MO169: 6, 7-2, 35-2; [Old: 6, 30] + MDSAP - USA - 21 CFR 830.30(h) + MDR - Article 10.9 ¶3 (g) + MDD - Annex II (3.2)"</p> <p>"Design and Development: Top Management Commitment to Design and Development Process (MDSAP Chapter 5, Task 17, Site: 10578); (DIN)(EN) ISO 13485 - 4.1.3, 5.1, 5.5.1 + (DIN)(EN) ISO 9001 - 4.4, 5.1.1, 5.3, 8.4 + MDSAP - Australia - TG(MD)R Sch3 P1 Cl 1.4(5)(b)(ii) + MDSAP - Brazil - RDC ANVISA 16/2013: 2.2.1 + MDSAP - Japan - MO169: 5, 10, 15 + MDR - Article 10.9 ¶3 (c) + MDD - Annex II (2, 3.1)"</p> <p>EN ISO 18562 (Biocompatibility evaluation of breathing gas pathways)</p>
Brief description of processes or activities evaluated to demonstrate what was audited related to the listed key QMS documents and records reviewed below considering inputs, outputs, and measures	<p>*****Trails (GP)</p> <p><u>D&D #1 - Identification of devices subject to design and development procedures; technical documentation (GP)</u></p> <p>The processes are defined and documented as set of procedures : DWAG IN 4200 is established ad applicable to medical and non-medical devices.</p> <p>The stage -gate is process is defined with 8 stages, whereas first 3 stage-gates form pre-design concepts phase.</p> <p>All design changes are following SOP Design Change Process.</p> <p>Start with Gate 3.0 Preparation ==> 4.0 Definition ==> 4.1 Design ==> 5.0 Realization ==> 6.0 Validation ==> 7.0 CE / Ramp-up / Market Launch ==> 7.1 Serial Production ==> Gate 8.0 Life Cycle/Change</p> <p>Changes are managed according to Design Change Process</p> <p>The system used for documentation for Design requirements is IBM Engineering Requirements Management Tool DOORS.</p> <p>The procedure defines criteria, as applicable for</p> <ul style="list-style-type: none">• new product development• module development• Upgrades and product change• Introduction of OEM or private label• Intro. Trading goods• Transfer of development, production or other disciplines

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	<p>SOPs for design and development were demonstrated and assessed during the audit – ref to list of documents for Designee and Development chapter.</p> <p>Additional country-specific requirements: Australia / Brazil / Canada / Japan - the organisation has identified no exclusion from Design control. All product families are controlled by the top-level design process.</p> <p><u>D&D #2 - Selection of a completed design and development project (GP)</u> 1. Smart Pilot View was selected based on the sampling plan to cover the product range of the company, as product with direct impact to safety and performance which was not yet evaluated during the surveillance cycle. The product was chosen as linkage to the on-going Technical Documentation review. 2. The product Connected Lung Protective Ventilation Analytics was chosen as verification if this can be a medical product in MDSAP scope. It was observed, the product is not a Medical Device, and therefore is out of scope for this audit.</p> <p>The introduction product performed: Smart Pilot View is monitoring and predication software for an Anesthesia application. The software displays and logs the dosage of intravenous and volatile drugs administered in human being. Additionally, it calculates the drug effect based on pharmacokinetic models and the drug interaction as guidance for treatment. Current release is 3.03 The devices classification is IIb according to MDR and MDD. The Device is currently MDD , and under MDR TD review.</p> <p>Classification Codes SmartPilot View 11213764_00 IfU_SPV_SW_3.03.n_9512901_1_2022-11_en Instruction for Use Smart Pilot view IfU_Supplement_SPV_SW_3.0n_9054332_11_2022-12 Compatibility with other devices Smart Pilot View</p> <p><u>D&D #11 - Clinical evaluation and/or evaluation of medical device safety and performance (GP)</u> Smart Pilot View Clinical evaluation and clinical investigation processes are established. CE is performed as a part of design and validation process and is documented in CER. CERs are organized to be grouped in "CER-families" if only possible. Aspects for a CER family: Similar or same intended purpose (similar literature search) etc. The process is set up with a main SOP DCS IN4250-110-en-03.00_Clinical Evaluation is the main SOP for MDR compliance, a separate SOP is available for the products under MDD IN 4251. Clinical performance and clinical benefit are mainly processed by the Clinical Affairs Team whereas clinical risks and clinical safety is assessed in the frame of the RM in close collaboration with the clinical / medical expert, this assessment is then fed back into the CEP/CER. Literature searches are conducted for the state of the art and the MDuE, for performance / benefit and safety. Search criteria are defined in the CEP and are generated according to the PICO approach. Preclinical data based on applicable standards are considered in CEP and CER. Review of Postproduction Information Report (RPPIR): this assessment is used for updates from the post-market phase on a regular basis. The complete CER is re-assessed when above listed documents are created to confirm or revise the contents. This approach is described in the main CER SOP.</p> <p>For the sampled device Smart Pilot View: Latest clinical evaluation covered by clinical evaluation plan – shown during the audit, Clinical evaluation report was demonstrated: 11149213_02 11149213 02 Clinical Evaluation Report Released</p> <p>Confirmation of Applicability (CoA): this assessment is used if new, not clinical information is available it will be integrated into an already existing CER-family with the next periodic update.</p> <p>PMCF Process: DWAG IN4250 Clinical Evaluation explains the process and documentation for PMCF Report established for that process. In step 17 of CE Process the decision on PMCF activities is done. There is PMCF Plan Template, PCF Checklist and PMCF plan includes need for PMCF, objectives, type of activity, description, rationale for appropriateness, timeline, summary of activities, evaluation of clinical data relating to equivalent or similar products, risk management report.</p> <p>In case of sampled product Smart Pilot View, PSUR contains statement that PMCF is fully based on PMS surveillance there is no need on active PMCF apart from Routine PMS</p> <p>It was explained that the SSCP process is not applicable as there are no class III devices manufactured. Post-market phase: update of CERs, the frequency depends on risk class and innovation status. Frequency is 2 to 5 years until end of production plus 7 years, or end of service and 2 more years.</p> <p>Additional country-specific requirements: Australia (TGA): Clinical Evaluation Reports includes the clinical evidence based on PMS history of the device. This can be presented by Literature search in line with IN4250 - Template - Literature Search</p> <p><u>D&D #12 - Software design and development (GP)</u> The Development of Software follows the V-Model approach.</p>

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	<p>From design and development plan, software requirements, software architecture, detailed design, implementation of software units, the process includes the Software classification (medical devices) DWAG-IN42_A05 – specific requirements for software.</p> <p>Most of the Software are class C, with some exceptions in class B,</p> <p>Unit testing is done by code review (by at least 2 people based on the Code Guidelines), Static Code Analysis, and automated unit tests.</p> <p>After the unit test have been completed, the Software will be integrated, which is continuously happening. When more items are affected by the change, there will be additional tests performed to prove correct functionality.</p> <p>The system tests will be then performed, to prove that the Software Requirements have been implemented and are fulfilled.</p> <p>After the Software System test is closed, and additional system tests which are performed together with the Hardware components. The results of the verification will be documented in a report, for the Software, also for the whole system.</p> <p>After the release of the Software, a regulatory check will be done to determine if additional activities with regards to normative requirements should be performed.</p> <p>Cybersecurity is also included in the Software development. There will be a thread analysis performed. The inputs for this analysis TR 60601-4, thread analysis template, system architecture, among others. The output for the process is the thread analysis which flows into the risk analysis process of the device, where the corresponding measures will be set. Verifications of cybersecurity measures follow the risk management and software development process.</p> <p>Anomalies are classified as serious, significant, important, noticeable or no effect. CIN-Classification critical important notable.</p> <p>Example ///SW Smart Pilot View -design change to Rev 3.03///</p> <p>The Software designed is performed in line with requirement of ISO62304. INSPECTION REPORT</p> <p>IEC 62304 process inspection by the accredited test lab Product Qualification, Drägerwerk AG & Co.KGaA was demonstrated during the audit.</p> <p>Software Class according IEC 62304 is determined Class B (According to the risk assessment table, the expected harm that could result from software failure is limited to “minor”). – observed in 5.1 Product Risk Management Report - 11149328_03</p> <p>The process was performed under the guidance of design change process DWAG IN4230 Design Changes, the changes were followed by verification and validation prior to release, which was sampled and assessed during this audit.</p> <p>The devices validation is defined in design Process IN4200. The step is performed between the Gate 6.0 and gate 7.0</p> <p>Following inputs and outputs were regarded for the Validation stage</p> <ul style="list-style-type: none">- Usability evaluation- Validation plan- Validation summary report- Reliability Review- User requirements DR-00072766 Product requirement's Smart pilot base Line 2022-11-24T <p>Particular examples of product requirements were sampled during the audit and implementation was verified</p> <p>PR-SPV_309 mart Pilot shall support Wierda PK Model for the Muscle relaxant Rocuronium</p> <p>PR_SPV_ _297 Emanating patient data</p> <p>Clinical User requirements - -</p> <p>PR_SRV-543 The user shall be able to determine the patients current and future hypnotic and analgesic level related to the leveled intended by user.</p> <p>Verification process linked to user requirements via</p> <ul style="list-style-type: none">- Standards- Provision of clinical evidence that TSR matches the user requirement's- Comparison with similar devices- Usability Evaluation Formative and summative reports <p>DOORs system is in use for Traceability for of Inputs and outputs</p> <p>The Validation summary report: 11149414 Rev 00 Validation Summary report V00 2023-02-24 demonstrated during the audit.</p> <p><u>D&D #13 - Design and development change (GP)</u></p> <p>The process flow id defined in SOP IND 4200</p> <p>The process is implemented as a workflow in Pro-X.</p> <p>A change request is prepared and evaluated by quality assurance, project manager and the product manager, these changes could be improvement of changes triggered by post-production feedback.</p> <p>In the case the change influences materials, and these materials are used for other products, the change needs to be assessed by other PSB .Product Manager and/or other functions decide on the DCR (accept or decline).</p> <p>After the design change has been accepted, the design change project will be created. This includes the design change plan, change project, pre-tailoring investigation (central document about which components are affected, recommended solution and which design reviews should be met), Object List (components which are going to be change), List of deliverables (which documents should be change</p> <p>Example – design change to Rev 3.03</p> <p>The change for the design was summarized as PKG-2021-002776 Pre-tailoring investigation 18.02.2021</p>

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	<p>The changes were accumulated as following: DCR-2019-002082 labeling amassing - change of the labels size – SW only DCR-2021-002127 ISM-IEC TR60601-4-5 DCR-20201 003730 - approval of the Zeus IE</p> <p>The package summary is in process of implementation and is not accomplished as a packages, therefore this cannot be used for the full assessment.</p> <p>The example of the changes was assessed during the audit: The reports rare maintain in SAP in controlled way. 11134555 Design change review report - for the release 3.02n PKF-202-003043 The changes contained – addition IFU languages / languages added The design change evaluation review report</p> <p>DCR-2020-002999 IFU Translation for Slovakia 2020-06-02 Verified that the DCR was suitably documented, implemented and verified Validation Form PID Printing process 2020-12-17 The printed documentation report The complete Design change documented , the new tool ARAS used</p> <p>Australia, Brazil, Canada, Japan, US) The regulatory affairs department is also including in the pre-tailoring investigation considering the requirements for each country where the device is marketed and the notifications to be done previous to the approval of the change.</p> <p><u>D&D #14 - Design review (GP)</u> The design reviews are established and the content for each review is defined accordingly. For medical devices the reviews are performed according to DWAG IN4200-en-01.00 Design. The Design Sub Process contains five major Design Reviews on system level:</p> <ul style="list-style-type: none">• System Requirements Review• System Architecture Review• System Integration Review (for each integration loop).• Verification Readiness Review• System Validation Review <p>Besides these major Design Reviews on system level, there are additional Design Reviews that are part of other process steps that are required as completion criteria. Design Reviews have to be conducted according to IN4204. Design Review reports are records and have to be filed into the DHF. Example – Example ///SW Smart Pilot View -design change to Rev 3.03/// As this design project was controlled as design change , standard design review requirements were not applicable. The project was released as 11134555 Design change review report US Procedures ensure that participants include representatives of all functions concerned with the design stage being reviewed and an individual(s) who does not have direct responsibility for the design stage being reviewed.</p> <p><u>D&D #15 - Impact review of design and development changes on previously made and distributed devices (GP)</u> An evaluation of the impact of the changes on already delivered devices is included in the template for Pre-Tailoring Investigation PTI. For the examples taken, it was possible to follow the impact analysis and the corresponding activities to be performed on the devices on the field.</p> <p>Example ///SW Smart Pilot View -design change to Rev 3.03/// Drager has demonstrated PTI PKG-2021-002776 from 23.05.2022, which encompasses charges for Smart Pilot View such as DCR-2022-002200 and DCR-2022-002214</p> <p><u>D&D #16 - Design transfer (GP)</u> For Software products, the process for Design Transfer of medical software is performed according to DWAG IN4206 Software Approval and Design Transfer and is documented in DCS IN4206-110 The release and transfer includes the following steps:</p> <ul style="list-style-type: none">- Check software development plan and deliverables- Check software verification- Check list of non-conformities- Check Software Build- Assure reliable delivery -Assure reliable delivery of the released software without corruption or unauthorized change, and where media are used that contain the released software, address their replication, media labeling, packaging, protection, storage, and delivery. Documented as Plan for malware-free shipping- Create and upload Software Archive according to IN4206 ARAS Manual <p>Logistically relevant software needs to be transferred from development to production and service. The software executables become part of the DMR, stored in PLM SYSTEM, on DVDs or on a server with controlled access and configuration control. The following documentation structure is fully supported by PLM SYSTEM but is also applicable to other storage concepts.</p> <p>Example ///SW Smart Pilot View -design change to Rev 3.03/// Elements of approval and design transfer records as required by DCS IN4206 were requested and assessed during the audit: Verification summary report – 11149420 verification summary report Rev 08</p>

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	<p>SW 3.03 List of No-conformities after release 11149233 List of Non-conformities Ver 05 Usability evaluation Summary report – 11149411 Usability summary report Rev 00 Statement – no formative usability test report was performed after change – as no changes affected the the product 11149378 Smart Pilot Usability Summative Test Rev 01 Smart Pilot View Suability Specification – 111494 Rev 01 usability Specification – 11149378 Rev 01 Summative Usability Evaluation test report Ver 01 Product risk management report - 11143145 PSUR Ver 01 2022-10-12</p> <p>Brazil The product is released and electronically signed via SAP system</p> <p><u>D&D #17 - Top management commitment to design and development process (GP)</u> Based on the assessment of Smart Pilot View Update design project, Top management has demonstrated the commitment or design and development by providing the resources, systems and process.</p> <p>*****</p> <p>Trails of (HD)</p> <p><u>D&D 13 - Design and development change (HD)</u></p> <p>The process is established and documented in DWAG IN 42 30 design change. A change request is prepared and evaluated by quality assurance, project manager and the product manager, these changes could be improvement of changes triggered by post-production feedback. In the case the change influences materials, and these materials are used for other products, the change needs to be assessed by other PSB. Product Manager and/or other functions decide on the DCR (accept or decline). After the design change has been accepted, the design change project will be created. This includes the design change plan, change project, pre-tailoring investigation (central document about which components are affected, recommended solution and which design reviews should be met), Object List (components which are going to be change), List of deliverables (which documents should be change).</p> <p>Additional country-specific requirements: (Australia, Brazil, Canada, Japan, US) The regulatory affairs department is also including in the pre-tailoring investigation considering the requirements for each country where the device is marketed and the notifications to be done previous to the approval of the change. The design package needs to be approved, from quality and project management, and then it will be implemented (documented in DHR, DHF, work items). A design review will be performed when all the changes are ready for release. This includes an evaluation of the status of the changes and the documentation that was generated (quality and regulatory affairs). It will be proved at the end if regulatory changes have been done, and if the country organizations should be informed. At the end the materials/components will be released and finalized (Quality Assurance).</p> <p>Example Flow sensor: The product was previously purchased and delivered as a finished medical device and is now manufactured on Revalstraße. It have been a strategic decision. Additionally, the color of the hose was change and the shape of hose slightly modified. DCR 2020-001379 dd. 31 05.2020 / PKG 2020 000943</p> <p>Flow sensor classification: It is not active device as pressure measurement device per se is in the connected device itself (Oxylog). The flow sensor has no energy source (does not need it) and is non active as per MDR definition. The pressure is transfer to the end device (Oxylog) and is measured based on volume converting.</p> <p>The classification process and assignment of the EMND codes presented during the audit seems plausible and appropriate.</p> <p><u>D&D 14 - Design review (HD)</u> The design reviews are established and the content for each review is defined accordingly. For medical devices the reviews are performed according to DWAG IN4200-en-01.00 Design. The Design Sub Process contains five major Design Reviews on system level:</p> <ul style="list-style-type: none">• System Requirements Review• System Architecture Review• System Integration Review (for each integration loop).• Verification Readiness Review• System Validation Review <p>The issuing authorities for release including Tester, products owner, Quality and regulatory.</p> <p>USA: There are a process in place (DWAG IN4200-en-01.00 Design). The competences and roles reviewers are defined in DWAG IN4230 and DWAG IN4200. Design review have been audited (Verification and Design Change review).</p> <p><u>D&D 15 - Impact review of design and development changes on previously made and distributed devices (HD)</u></p>

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	<p>An evaluation of the impact of the changes on already delivered devices is included in the template for PTI. For the examples taken, it was possible to follow the impact analysis and the corresponding activities to be performed on the devices on the field. The impact of DCR was reviewed during the audit for biocompatibility test report and usability test report (Inspection Report No 21 -00620)</p> <p><u>D&D 16 - Design transfer (HD)</u> At the end of design and development the design has been transferred to the production site at Revalstrasse at Dräger. The design change steps are signed/ released in SAP by the click on the checklist status is visible who and when has releases each step. Additional country-specific requirements: (Brazil) The devices are released for production only after correct approval from the corresponding personnel, which includes quality assurance. The release is documented and signed accordingly.</p> <p>*****</p> <p>EN ISO 18562 (Biocompatibility evaluation of breathing gas pathways) (GM) See document: ISO 18562_questions for audit_v1_2023-07-14 filled on 20.09.2023 !!! *****</p> <p>***** (MSz) <u>DD11 - Clinical evaluation and/or evaluation of medical device safety and performance (MSz)</u> Verified that clinical evaluation was performed as part of design validation. Supplier Novinion GMBH Tübingen and Neanatologe Dr. Trips as Mitauthor des CER.</p> <p>Australia (TGA): Clinical Evaluation Report Babyleo TN500 SW1.05 -2020-01-08 Review of Post Production Information Report (Clinical) 2022-05-19 PMCF Plan Babyleo TN500 2022-07-25 PMCF Report not yet available PSUR Thermoregulation 2023-08-01</p> <p><u>DD12 - Software design and development (MSz)</u> Software design and development Since medical device contains software, verified that the software was subject to the design and development process. It could be confirmed that the software was included within the risk management process.</p> <p><u>DD13-15 - Design and development change Babyleo TN300 (MSz)</u> Verified that design and development changes were controlled, verified (or where appropriate validated), and approved prior to implementation. It also could be confirmed that any new risks associated with the design change have been identified and mitigated to the extent practical.</p> <p>DRÄGER Babyleo TN500 Both radiant warmer and neonatal incubator Introduced 2017 to the market, already MDR upgraded. ProX (SAP tool) is used for documenting Lifecycle Management changes. PKG-2021-001689 Q-Improvement Nozzle Opening PTI Pre-Tailoring Investigation PKG-2021-001689 closed 2022-01-24 Regulatory relevance of this change: - material stays the same; - Intended Use stays the same; - Production process stays the same; - Production tool gets an update - Current standard report remains valid - EN-60601-2-19 testings stay valid</p> <p>Product CAPA 97813 Humidifier leakage via pressure release port during operation assessed the need for a Field Action; result: no, therefore nozzles with existing diameter could be used up. Change Overview 2021-11-15 Assessment on Significance result: EU no, US Letter to File, CA annual renewal; <input type="checkbox"/> Letter to File: AMD 20, 2022-03-02, RCA Change of the Diameter of the opening of the humidifier nozzle to a larger size. Changes are handled via DCR Design Change Request to PSB Product Steering Board Product Steering Board consist of interdisciplinary team and manages the product changes latest after design transfer by selecting them combining and planning product changes according to the business objectives. Attendees are at least: Product Manager, Project Manager, Quality Assurance and Regulatory affairs; depending of the nature of the design change project, the PSB must be supported by subject matter experts.</p> <p><u>DD16 - Design transfer (MSz)</u> Determined that the design was correctly transferred to production. Work package "Industrial Engineer – Update production process" and Quality Engineer – update production quality process" and "Material Resource planner" have been completed as documented in Design Change Summary page 9.</p>

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	<p>*****GM</p> <p><u>DD13 - Design and development change ATLAN (GM)</u> Changes have to be verified and approved prior to implementation, which is done in the selected project. Requests can be triggered from anyone. Handling of change evaluation will be done in the tool "ProX". Changes have to be approved by Product -Manager/ProjectManager/Quality assurance. Design changes processing in general is defined in DWAG IN4230. After approval the change request will be transferred into change project with related evaluation and list of deliverables. Out put document of evaluation is: Pre-Tailoring investigation which serves for definition of mayor needed info and definition of responsibilities and needed reviews. It have to be evaluated whether additional input into risk analysis must be performed and effects on delivered products are checked for each request.</p> <p>Change to ATLAN 2.0 SW version was audited.</p> <p>USA: Verify that the organization obtained a new 510(k) or supplement to the pre-market approval if required [21 CFR 807]. 519 k for ATLAN 2.0 is available: 510 k FDA 2023, 07.23, K 230931, approved by James J. Lee S (ATLAN change 2.0)</p> <p>Canada: Verify that the manufacturer has a process or procedure for identifying a "significant change" to a Class III or IV medical device. Verify that information about "significant changes" is submitted in a medical device license amendment application [CMDR 1, 34]. All changes will be presented at a steering Board (weekly meeting) Members of the steering board are also from R&A. In this steering board it will be decided whether the changes are singificant. Quality assurance (also part of the steering board and change process handling) is responsible that the regulatory decision will be taken. This is defined in DWAG IN4230. A checklist for decisoon is available DWAG PQ2110 regulatory approval to market product. For the audited sample no Canada approval is planned.</p> <p>Australia: Verify that the manufacturer has a process or procedure for notifying the auditing organization of a substantial change to the design process or the range of products to be manufactured [TG(MD)R Sch3 Cl1.5]. Verify that the manufacturer has a process or procedure for identifying a proposed substantial change to the design, or the intended performance, of a Class AIMD or Class III device, and to notify the assessment body prior to implementing the change [TG(MD)R Sch3 P1 Cl 1.6(4)].</p> <p>If the Manufacturer is also a holder of a TGA Conformity Assessment Certificate, then the Manufacturer is also required to notify the TGA of these changes. Verify that Manufacturer has taken into account post-production feedback as an input to monitoring and maintaining product requirements and improving product realization processes. All changes will be presented at a steering Board (weekly meeting) Members of the steering board are also from R&A. In this steering board it will be decided whether the changes are singificant. Quality assurance (also part of the steering board and change process handling) is responsible that the regulatory decision will be taken. This is defined in DWAG IN4230. A checklist for decisoon is available DWAG PQ2110 regulatory approval to market product.</p> <p>PMS PLAN ATLAN/PSUR ATLAN have been audited. Market Clearance MC Form AUST(New Zealand), 09.06.2023 ATLAN X, 2.0</p> <p>Japan: For the Marketing Authorization Holder, confirm if the Marketing Authorization Holder has submitted a new application, a change application, or a change notification to PMDA/ a Registered Certification Body, when applicable.[PMD Act 23-2-5.1, 23-2-5.11, 23-2-5.17, 23-2-23.1, 23-2-23.6, 23-2-23.7]. For the Registered Manufacturing Site, confirm if the site has a mechanism to communicate with the Marketing Authorization Holder about device modifications, so the Marketing Authorization Holder can take appropriate actions. If a critical medical device modification has happened in the Registered Manufacturing Site, confirm if the Registered Manufacturing Site has communicated with Marketing Authorization Holder about the change [MHLW MO169: 29]. All changes will be presented at a steering Board (weekly meeting) Members of the steering board are also from R&A. In this steering board it will be decided whether the changes are singificant. Quality assurance (also part of the steering board and change process handling) is responsible that the regulatory decision will be taken. This is defined in DWAG IN4230. A checklist for decisoon is available DWAG PQ2110 regulatory approval to market product. Market Clearance MC Form Japan, 20.01.2023 ATLAN X, 2.0</p> <p>Brazil: If the medical device evaluated is already registered/notified with ANVISA, verify that the design change was correctly and promptly submitted to ANVISA for approval, when applicable [Brazilian Law 6360/76 - Art. 13]. All changes will be presented at a steering Board (weekly meeting) Members of the steering board are also from R&A. In this steering board it will be decided whether the changes are singificant. Quality assurance (also part of the steering board and change process handling) is responsible that the regulatory decision will be taken. This is defined in DWAG IN4230. A checklist for decisoon is available DWAG PQ2110 regulatory approval to market product. It is not planned to get the market approval for the audited change sample for Brazil.</p> <p><u>DD14 - Design review (GM)</u> Design review for Design changes is described in the procedure DWAG IN4230 and implemented in the design and development plan of the selected project. The Review steps are individually defined in PKG-2021-003936. After completion of specific design phases a design review is performed and approved by defined personnel (including add. independent and competent members). Participants in the reviews of the selected project include representatives of functions concerned with the design and development stage being reviewed, as well as any specialist personnel needed. These were in the selected case</p>

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	<p>:System Designer and Leader of Verification approve Verification Review, Change Review will be approved by Project Leader, Quality assurance and Regulatory Affairs.</p> <p>USA:</p> <p>Verify that procedures ensure that participants include representatives of all functions concerned with the design stage being reviewed and an individual(s) who does not have direct responsibility for the design stage being reviewed, as well as any specialists needed [21 CFR 820.30(e)].</p> <p>The competences and roles reviewers are defined in DWAG IN4230 and DWAG IN4200.</p> <p>Two samples of Design review have been audited (Verification and Design Change review).</p> <p><u>DD15 - Impact review of design and development changes on previously made and distributed devices (GM)</u></p> <p>Assessment of Design Changes is defined in DWAG IN4230</p> <p>Design changes are reviewed for effects on products already delivered. This will be documented and approved in PKG-2021-003936, Pretailoring investigation. This document has been audited for ATLAN 2.0.</p> <p>Impact review of design and development changes on previously made and distributed devices.</p> <p>See PTI PKG-2021-001689 Section assessments</p> <p><u>DD16 - Design transfer (GM)</u></p> <p>The design change ATLAN 2.0 was correctly transferred into production.</p> <p>Design change transfer is defined in DEMF GM2110 and includes checks for availability of all needed material. The check will be documented in OA.</p> <p>Brazil:</p> <p>Confirm that the manufacture ensures that the design is not released for production until its approval by the persons assigned by the manufacturer and that the persons assigned review all records required to the design history file in order to ensure it is complete and the final design is compatible with the approved plans, prior to its release. Confirm that this release, including date and manual or electronic signature of the responsible is documented [RDC ANVISA 16/2013: 4.1.9, 4.1.11].</p> <p>Approval of OA (change transfer) will be performed by Quality assurance.</p> <p>The OA includes the check of all needed deliverables. The OA ATLAN 2.0 have been audited. Triggered by the Change package and specifically for SW changes among others e.g. the IFU have been adjusted.</p> <p>*****</p> <p>Tasks from MGa</p> <p>*****</p> <p><u>D&D #1 (MGa)</u></p> <p>Process Description:</p> <p>[ISO 13485:2016: 4.1.1, 4.2.1, 7.1, 7.3]</p> <p>Devices that are, by regulation, subject to design and development procedures are identified. Main process is DCS IN4200 that regulates the development of new devices. All design changes are following SOP Design Change Process.</p> <p>Gate 1 and 2 of main process are research phases, e.g. marked investigation, which is optional. Technical documentation in terms of Medical Device History is conducted, at each gate appropriate reports are provided. The fulfillment of the GSPRs are planned and considered.</p> <p>For the development of Humidstar 2+LL the design and development phase started in gate 3.0. Technology and market are already known.</p> <p>Start with</p> <p>Gate 3.0 Preparation: Design and development will be specified; the product requirements finalized,</p> <p>Gate 4.0 Definition: e.g. technical system requirements, Usability, plan validation; finalized with System requirement review (SRR)</p> <p>Gate 4.1 Design: Detail Q Targets based on SA (system architecture) freeze of requirements.</p> <p>Gate 5.0 Realization: system integration review, implementation of design; VRR Verification readiness Review, Finalize Design Transfer</p> <p>Gate 6.0 Validation: System validation review, official end of development</p> <p>Gate 7.0 CE marking: Ramp-up / Market Launch: monitoring, in a narrow scheme</p> <p>Gate 7.1 Serial Production: final production site/ one line and one tool for the device Humidstar 2+LL</p> <p>Gate 8.0 Life Cycle/Change: targets in quality, financial, on market</p> <p>The process for Humidstar 2+LL had been defined as a new development:</p> <p>The Humidstar 2+LL had been designed as new product development.</p> <p>The Humidstar 2+LL is classified as class IIa product under MDR,</p> <p>The filter and HMEs are currently registered in the following MDSAP countries:</p> <ul style="list-style-type: none">- Australia- Brasilia- Canada <p>The regulatory department confirms that the Humidstar 2+LL are not registered in Japan and USA.</p> <p>The procedure defines criteria, as applicable for</p> <ul style="list-style-type: none">• new product development• module development• Upgrades and product change• Introduction of OEM or private label• Introduction of Trading goods• Transfer of development, production or other disciplines <p>Changes are managed according to Design Change Process</p> <p>According to DWAG IN 4230 Design Changes, design change request (DCR) can be issued by anyone. Project Manager with team of QM and R&D the request will be assessed.</p> <p>Change process flow will be individually decided depending on the request.</p>

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	<p>Australia: The technical documentation will be issued in parallel to the development phase, end with the successful CE marking.</p> <p>Brazil/ Canada/ Japan: In general a List of applicable standards, depending on which countries included in product requirements, is available.</p> <p>Key process documents reviewed: DWG In4200en 01.00 Design, 2021-10-01 Process describes the Stage gate approach: Gate 3.0-8.0 DWAG IN 4230 Design Changes, en, 05.00, 2023-06-30</p> <p>*****</p> <p>Specific Personnel Competency and Training ISO 13485: 6.2 Roles profiles are defined for each role. The roles are implemented in the electronic training tool, the appropriate training are linked to the required competence trainings matrix. Training needs are identified. Training can be conducted external, classroom training or self-training. The training pensums are monitored annually.</p> <p>Documents: DEALL HR3400 Employee Qualification Process, 2021-10-15</p> <p>Records: TC Manager Records (Qualification Matrix) for M.H.: Screenshot Training tool "TC Manager": personalized: Roles: Betriebsmittelbeauftragter; Leader Verification; Verification engineer is finalized Planned training: Project Management trainer planned 2023-11-09 S.B.: Roles: Lifecycle manager, Medical Device Acts, (Training completed) L.L: RA: Special and General Work instruction Training on ISO 13485; MDR, MDSAP-all completed. *****</p> <p><u>D&D #2 (MGa)</u> ISO 13485:2016: 4.1.1, 4.2.1, 7.1, 7.3.] Design and Development Project "Air Force One" (AFO) had been in scope of the audit, especially for Humidstar 2+LL, as this device is regarded as a new development. The device is dedicated for neonates. The UDI system had been used and a Basic UDI is dedicated to the device. The device under review is the HME (heat and moister exchanger): Humidstar 2+LL The HME parts are supplied by supplier from Sweden ULAX. The HME consist of the two parts of the case (top and bottom) and the medium "foam", which is impregnated. The example had been selected due to transfer of production. The device was not in scope of an audit and it is listed on MEDF0325.01, Rev. 11 and is certified under MDR certificate G10 010578 0039 Rev. 09 as R0401 - VENTILATION FILTERS: HME HumidStar 2 Plus Luer-Lock - MP05840 0404867512080436K19T010SC R0401 MDN 1201</p> <p><u>D&D #3 (MGa)</u> ISO 13485:2016: 4.2.1, 7.1, 7.3.2 Process Description: The process DWG In4200en 01.00 Design, 2021-10-01 requires 5 design reviews at the end of the gate phases 3.0-8.0. For the project of HME SRR: System requirement reviews SAR: System Architecture (not applicable for the HME project) SIR: System integration review (not applicable for the HME project) VRR: Validation requirement review SVR: System validation review</p> <p>Description of requirements: Process steps and reference to tools are listed in attachment A02, including rolls of participants. Templates for reviews are implemented-</p> <p>Australia: Effective planning for the design and development steps are documented, as verified in task DD-1.</p> <p>Canada: As the device under review is not a class IV device this had not been reviewed in particular. However, the process outlines the specific quality practices, resources and sequence activities relevant to the device. Key process documents reviewed: DWG In4200en 01.00 Design, 2021-10-01</p> <p><u>D&D #4 (MGa)</u> ISO 13485:2016: 4.2.1, 7.3.1, Process Description: The sampled project meets the requested requirements. All sampled product designs follow the global DMS IN4200 development process.</p>

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	<p>List of applicable standard for the HME device are listed within the PTS. "Production and test specification for medical breathing filters and HME" US: A process is in place to identify the applicable requirements.</p> <p><u>D&D #5 (MGa)</u> ISO 13485:2016: 4.2.1, 5.2, 7.2.1, 7.3.3; Process Description: Design Inputs are for example user needs, customer functional, performance and safety requirements, intended use and regulatory requirements. For each project there is an applicable list of standards documented which needs to be applied within the development phase. Regulatory, functional and safety requirements as well as intend use are subject to SOP and are also addressed in the design change by tailoring of the development process. Requirements are checked for conflicts in the system requirements review report. Risk management outputs serve as design input. For US: No 510k is applicable for the selected device</p> <p><u>D&D #6 (MGa)</u> ISO 13485:2016: 7.3.3 Process Description: The Design Inputs are unambiguous and do not conflict with each other. Requirements are checked for conflicts in the system requirements review report. All requirements are checked and approved within the SAR. For Humidstar 2+LL project no Management commitment and Kick off meeting was not requested as the product portfolio AFO was already approved. For the development process of Humidstar 2+LL as part of the portfolio the gates 1 & 2 had been skipped. The list of deliverables (required records) had to be fulfilled. Australia: Relevant Medical Device Standards are considered and in scope of the development process for Humidstar 2+ LL</p> <p><u>D&D #7 (MGa)</u> ISO 13485:2016: 4.2.1,4.2.3, 7.3.4 Process Description: Design and development outputs (e.g. device specifications) are traceable to the design and development inputs. Specifications are also traceable to the verifications. Traceability description for the change project reviewed.</p> <p>For the Medical Device File a documentation matrix is available which shows the locations of the applicable specification, bill of material, applicable tests. DEALL PQ3130 Control of Documents and Records, Rev.4, 2023-07-06: A 02, 2023-09-12: Dokumentationsmatrix: Device master record (DMR): Parts of DMR predefined for design transfer. Partial specification, and other specification are listed.</p> <p>The cross functional team decided supplier ULAX, Motala Sweden, producer of the HME foam.</p> <p><u>D&D #8 (MGa)</u> ISO 13485:2016: 4.2.1, 7.1, 7.3.3, 7.3.4; Process Description: General the risk management is applied,. A complete Risk Management process according to ISO 14971 is implemented and is part of the design and development. Risk acceptance criteria are defined. Risk management has been adapted for change and is up-to-date. The risk management includes the identification of risks, its assessment and the definition of measures to counteract those risks. Companywide risks are assessed; Severity and Probability are defined, and measurable with results in defined classes "frequent, occasional, low, impossible". US: Identified risks are reduced as far as possible, reduction of risks are dedicated to a new assessment to avoid implementation of new hazards.</p> <p><u>D&D #9 (MGa)</u> ISO 13485:2016: 7.1, 7.3.6, 7.3.7; Process Description: In the design and development verification/validation the effectiveness of the risk control measures are verified. Verification testing is a central part of the design process and is typically conducted in an independent design verification department. These activities include testing against international standards.</p> <p><u>D&D #10 (MGa)</u> ISO 13485:2016: 4.2.1, 7.3.7; Process Description: The development validation phase shows that the design meets the intended use. Australia: environmental conditions are considered and described within the IFU, e.g. temperature, re. humidity and ambient pressure, see DD-1</p>

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	<p><u>D&D #11 (MGa)</u> ISO 13485:2016: 4.2.1, 7.3.7; Process Description: The clinical evaluation is part of the technical documentation. The process IN 4250 is outlined in BIC process management system: 1. Step: new or existing product change-for new 2. Clinical development plan necessary, including initial literature review, clinical study necessary 3. Pre clinical investigation necessary Design change: Via DC request=> significant change, nonsignificant changes results in an Amendment => assessment results in new clinical evaluation Literature search report: separate as output document of clinical evaluation</p> <ul style="list-style-type: none">• CEP• CDP• PSURs• PMCF plan=>activities=> evaluation report• SSCP necessary=> not available at Dräger <p><u>D&D #12 - n/A (MGa)</u></p> <p><u>D&D #13 (MGa)</u> Process Description: The Design and Development Change is described in DMS IN 4230 Design Change Process. The reviewed project "Air Force One" was conducted as a new product development. General description of Design changes: DCR design change request will be submitted Each employee can submit this, at the Review a decision will be made if the project will be started or not DCR (design change request) will be proceeded with Pro X, plug in of SAP deliverables, Object changes, e.g. drawings, specs, Change specific review, market approvals Market authorization will be handled by RA Change accepted and implementation Key process documents reviewed: DMS IN 4230 Design Change Process</p> <p><u>D&D #14 (MGa)</u> ISO 13485:2016: 4.2.1, 7.3.2, 7.3.5; Process Description: After completion of specific design phases a design review of defined personnel (independent) has been performed. A formal design review needs be conducted and documented before closure of a specific Design Phase. US: Applicable representatives are involved in the development process and approval process. For further description, please see also task DD-3</p> <p><u>D&D 15 (MGa)</u> ISO 13485:2016: 7.3.9; Process Description: The Design and Development Change is described in DMS IN 4230 Design Change Process. The reviewed project "Humidstar 2+LL" was conducted as a new product development.</p> <p><u>D&D #16 (MGa)</u> ISO 13485:2016: 4.2.1, 4.2.3, 7.3.8 Process Description: At the end of design and development the design has been transferred to the production site at ULAX, contracted supplier. Approved part specification are mandatory an OA (Object Approval) can be issued. OA difference between new products, changes, prototype or logistical changes. Responsibility matrix is given. OA is implemented in OX -change tool in SAP. All relevant activities have to be finalized before OA started. Review by D&D: complete and correct Australia: The release, includes date and signature of the responsible (manual or electronic)is documented MRP Material resource planning: all data in SAP Buy workflow has to be finalized before outsourced manufacturing starts Part FAI required=> quality confirms FAI is ok Label data: release of label department Confirm end of OA: released by R&D, RA & Quality</p> <p><u>D&D 17 (MGa)</u></p>

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	<p>ISO 13485:2016: 4.1.3, 5.1, 5.5.1</p> <p>Process Description: Based on the assessment of the development process the management provides the necessary commitment to the design and development process. Management provides commitment, independent reviews are required by process. A compliance procedure does exist.</p> <p>*****</p> <p>MDR Clinical Evaluation Report Babyleo TN500 SW1.05 -2020-01-08 PMCF Plan Babyleo TN500 2022-07-25 Clinical evaluation and performance evaluation in line with the state of the art (PSUR Thermoregulation 2023-08-01)</p> <p>MDR Software development process takes into account the principles of development life cycle, risk management, including information security, verification and validation.</p> <p>EU MDD / MDR MDD Annex II 3.2, 3rd paragraph (c), 9th indent MDR 2017/745 - Article 10(3), 61 and Annex XIV Completion of clinical evaluation / performance evaluation including PMCF / PMPF Clinical evaluation report was demonstrated: 11149213_02 11149213 02 Clinical Evaluation Report Released</p> <p>MDR 2017/745 - Article 10(3), 61.9 Clinical evaluation for products under Annex XVI. – n/a</p> <p>MDR 2017/745 - Article 10(3), 62 and Annex XIV Clinical evaluation and performance evaluation in line with the state of the art (PSUR) PSUR is established and documented, according to PSUR, the PMCF is limited to the PMS process only. 11143145 PSUR Smart Pilot View Ver 01 2022-10-12</p> <p>MDR 2017/745 - Article 32 – Class III and implantable medical devices Summary of safety and clinical performance (SSCP) – N/A, there are no class III devices manufactured.</p> <p>*****</p> <p>Clinical evaluation and/or evaluation of medical device safety and performance (GP)</p> <p>FOLLOW UP of point 7 to project 1990804: CC 300 - Response DR2 Dräger The action item was reviewed during the audit. The CEP Template, CEP and CER including CV of CC 300 device were reviewed. The statement checked and accepted by TDA in the deficiency report (Order No 713298423) has been included in new CE Procedure IN 4250, CEP template, CEP of CC 300 and updated CER of CC 300 device. The qualifications of evaluators are documented in section 9, qualifications are documented according to the MEDDEV 2.7/1 revision 4.</p> <p>Records: DWAG IN 4250 Clinical Evaluation -en-04.00 dd 26.06.2023 DWAG IN 4250 en. 04.00 CEP Template CEP DWAG IN 4250 en. 04.00 Connectivity Converter CC 300 CEP -CC 300 ID 11224385 revision 01 released 2023- 09-13 CER-CC300 ID 11224384 revision 01 signed 2023-09-15.</p>
Reviewed documents and records (identification and revision)	<p>GP DWAG IN 4250 Clinical Evaluation -en-04.00 dd 26.06.2023 DWAG IN 4250 en. 04.00 CEP Template CEP DWAG IN 4250 en. 04.00 Connectivity Converter CC 300 CEP -CC 300 ID 11224385 revision 01 released 2023- 09-13 CER-CC300 ID 11224384 revision 01 signed 2023-09-15.</p> <p>*****GP DWAG IN4000: Develop Product, Rev. 14.00 DWAG IN 4200-en01.00 Design DWAG IN4202 Usability Evaluation DWAG IN4203 Product Verification DWAG IN4204 Design Related Product Reviews Rev 02.00</p> <p>DWAG IN4100: Project Management_en_02.00 DWAG IN4300: New Product Introduction, Rev. 09.00</p> <p>Classification Codes SmartPilot View 11213764_00 IfU_SPV_SW_3.03.n_9512901_1_2022-11_en Instruction for Use Smart Pilot view</p>

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	<p>IFU_Supplement_SPV_SW_3.0n_9054332_11_2022-12 Compatibility with other devices Smart Pilot View</p> <p>DWAG IN4250 Clinical Evaluation Rev.04.00 DWAG IN4251 Clinical Evaluation (MDD) Rev 00 111494913 Smart Pilot View Standalone Validation Plan Ver 01 11149213_02 11149213 02 Clinical Evaluation Report Released 11143145 PSUR Smart Pilot View Ver 01 2022-10-12 4.1 GSPR -11233802_00 Smart Pilot View DDWAG IN4205-en 02.00 Software design DWAG IN4206 Software Approval and Design Transfer Ver 02.00 11149414 Rev 00 Validation Summary report V00 2023-02-24 Product Risk Management Report - 11149328_03 Product Risk Assessment Table - 11221004_03 Validation Summary Report - 11149414_00 2 6.2 SPV_IEC62304 - 11244067_00 INSPECTION REPORT IEC 62304 6.2 SPV_IEC62366_1 - 11245524_00 TEST REPORT IEC 62366-1:2015 6.2 SPV_IEC82304 - 11244450_00 Test Report IEC 82304-1:2016 UUser manual Ver 2.02 DR-00072766 Product requirements Smart pilot base Line 2022-11-24T</p> <p>DCR-2019-002082 labeling amassing - change of the labels size – SW only DCR-2021-002127 ISM-IEC TR60601-4-5 DCR-20201 003730 - approval of the Zeus IE 11134555 Design change review report - for the release 3.02n PKF-202-003043 DCR-2020-002999 IFU Translation for Slovakia 2020-06-02 Validation Form PID Printing process 2020-12-17 PTI PKG-2021-002776 from 23.05.2022 11149233 List of Non-conformities Ver 05 Smart Pilot View SW 3.03 11149420 verification summary report Rev 08 Smart Pilot View 11149411 Usability summary report Rev 00 11149378 Smart Pilot Usability Summative Test Rev 01 111494 Rev 01 usability Specification Smart Pilot View 11149378 Rev 01 Summative Usability Evaluation test report Ver 01 11143145 PSUR Ver 01 2022-10-12</p> <p>DWAG IN4230 : Design Changes DWAG IN4230 - en - 05.00 , Rev. 05.00 , reviews defined, and OA (design transfer) „start creation and change material MASTER data” , responsibilities defined. DWAG IN4200 : Design DWAG IN4200 - en - 01.00 , Rev. 01.00 DEMF GM2110 : Creation and Change of Material Master Data for Global Portfolio DEMF - GM2110 - en - 01.00 , Rev. 01.00 DWAG IN4250 : Clinical Evaluation DWAG IN4250 - en - 04.00 , Rev. 04.00 DEMF PQ2000 : Post Market Surveillance System DEMF PQ2000 - en - 02.00 , Rev. 02.00 DWAG IN4230 : Design Changes DWAG IN4230 - en - 05.00 , Rev. 05.00 DWAG IN4200 : Design DWAG IN4200 - en - 01.00 , Rev. 01.00 DWAG PQ2110 : Regulatory Approval to Market Product DWAG PQ2110 - en - 03.00 , Rev. 03.00 DWAG PQ2110 : Regulatory Approval to Market Product DWAG PQ2110 - en - 03.00 , Rev. 03.00</p> <p>*****</p> <p>Records <u>DD11 (MSz)</u> Clinical Evaluation Report Babyleo TN500 SW1.05 -2020-01-08 Review of Post Production Information Report (Clinical) 2022-05-19 PMCF Plan Babyleo TN500 2022-07-25 PMCF Report not yet available PSUR Thermoregulation 2023-08-01</p> <p><u>DD12 (MSz)</u> Softwareänderung SW1.06 PKG2020-003896 Change Specific Design Review Report TN500 SW1.06 Product Risk Management report RM 37, T500_HA 1.42</p> <p><u>DD13 (MSz)</u> PKG-2021-001689 Q-Improvement Nozzle Opening PTI Pre-Tailoring Investigation PKG-2021-001689 closed 2022-01-24 Approval Design Change Package 2022-05-06 CSDRR Change Specific Design Review Report for PKG-2021-001689 2022-05-03 Design Change Summary Final PDF PKG-2021-001689_PKG Export_2022-05-06_MT3.pdf DCR-2020-001820 "Vergrößerung des Nozzles zur Wasserdampfauslassöffnung"</p> <p>***** (HD) DWAG IN 4250 Clinical Evaluation -en-04.00 dd 26.06.2023 DWAG IN 4250 en. 04.00 CEP Template CEP DWAG IN 4250 en. 04.00 Connectivity Converter CC 300 CEP -CC 300 ID 11224385 revision 01 released 2023- 09-13 CER-CC300 ID 11224384 revision 01 signed 2023-09-15.</p>

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	<p>DDWAG4230-en-05.00 design changes PQ 2010 Regulatory Affairs Zulassungprocess MDR 108 – 030 1.1.6 Classification _codes Carina & Oxylog Breathing Circuit PQ 2010 Regulatory Affairs- Zulassungprocess MDR 108 – 030 1.1.6 Classification _codes Carina & Oxylog Breathing Circuit DCR 2020-001379 dd. 31.05.2020 / PKG 2020 000943 PTI - PSB 242 created 11.003.2020 BioComp Report -ID 11228066 Carina and Qxylog BC PrM Report 29.11.2022. Inspection Report No 21 -00620 – PR 001 Rev 01. DCR Approval record from SAP 18.02.2022 signed by PO/ QA System Validation Review Report Breathing 30-11-2022 ID - 11 221639 IFU - 9511030 version edition 4</p> <p>***** (GM)</p> <p><u>DD13 (GM)</u> Design change Request DCR -2021-006006 ("Cyber Anteil ATLAN 2.0"), status changed in pro X from Z00 to Z06 (which serves as signature), accepted by Kirstner (Product Manager as required in process), date 14.01.2022, assessment of change evaluation and decision regarding significant change is documented in this document. PKG-2021-003936, Pretailoring investigation, ATLAN SW upgrade (2.0) last update 14.01.2022, functional enhancement : Cyber Sec, bug fixes, recruitment features, Improvement of GUI, Insp Exp rate , Auto on and others, Design review steps are defined. Influence assessment on products in the market, products and stocks not affected, Cyber updates state of the art(MDR only for ATLAN 2.0) electronic signature on: Design Change Package Export, 14.10.2022, signed by Project Leader and Quality assurance including Design Change plan ATLAN and Pretailoring investigation.</p> <p>510 k FDA 2023, 07.23, K 230931, approved by James J. Lee S Market Clearance MC Form Japan, 20.01.2023 ATLAN X, 2.0 Market Clearance MC Form AUST(New Zealand), 09.06.2023 ATLAN X, 2.0</p> <p>11100333 PMS Axxx family, rev 0, approved 25.08.2023, yearly evaluation also ATLAN. 11249101 PSUR Axxx Familiy, rev 0, chapter 6.2, data from 2022, conclusion, benefit risk ratio not attached, approved 30.03.2023. Risk assessment table has updated during 2022, Hazard analysis ATLAN 2.0 , 6.22 approved 05.01.2023, Cyber included, typos , some acceptance rationales adjusted.</p> <p><u>DD14/15/16 (GM)</u> Verification Readiness Review Report ATLAN 2.0, approved by System Engineering and Verifiction Leader 12.05.2021. 11159497 Change specific design Review Report ATLAN 2.0, v 00, approved 12.07.2022 by Project Leader, Quality assurance An R&A responsible person. Design transfer OA specific Object List 2022-MT-1426, approved 16.06.2022. PKG-2021-003936, Pretailoring investigation, ATLAN SW upgrade (2.0) last update 14.01.2022, functional enhancement : Cyber Sec., bug fixes, recruitment features, Improvement of GUI, Insp Exp rate , Auto on and others, Design review steps are defined. Influence assessment on products in the market, products and stocks not affected, Cyber updates state of the art(MDR only for ATLAN 2.0) electronic signature on: Design Change Package Export, 14.10.2022, signed by Project Leader and Quality assurance including Design Change plan ATLAN and Pretailoring investigation.</p> <p>*****MGa TC Manager Records (Qualification Matrix) for M.H.: Screenshot Training tool "TC Manager": personalized: Roles: Betriebsmittelbeauftragter; Leader Verification; Verification engineer is finalized Planned training: Project Management trainer planned 2023-11-09 S.B.: Roles: Lifecycle manager, Medical Device Acts, (Training completed) L.L.: RA: Special and General Work instruction Training on ISO 13485; MDR, MDSAP-all completed.</p> <p>Regulatory approval plan Air Force One, Rev.03 , 2021-11-30 Simon Barz: product management In planning: Humidstar 2+LL with rev.03; approved function: Part no for Humidstar 2+LL: MP05840, in chapter 1.5.2: planned to be marketed. • Europe CE • USA • Canada • Japan • Brazil Not planned for Australia MDR: G10 010578 0039 Rev. 07, valid until 2025-03-17, MDR 2017/745 Annex IX, class IIa, Humidstar 2+LL is currently marketed only in CE area Australia: - Brasil: HME Humidstar 2+LL New medical device registration incl Inmetro Cert.</p>

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	<p>Canada: new class II medical device license USA: HME class I, 510 (k) exempted, Japan: Approval procedure acc. to MHLW Pharmaceutical Affairs Law. List of regulatory requirements, Rev. 5: 2021-10-16: up date of Humidstar 2+LL Colour coded for standard: orange for product requirements Requirements for all defined countries: AUS/ JAP/ CAN/ BRA Version change of standards will be implemented via design change control</p> <p>Design and Development plan 101039_12: Roles are defined Change control: when changes will be identified during the project. TSR Technical system requirements V18, 2022-10-13, Environmental requirements. Ergonomic aspects, biocompatibility, anesthetic agents, ISO 18562, usability time 30days, Condensate contact (indirect contact to patient, not sterilized, Technical mechanical: requirements: conical shape for both cylinders, luer lock requirement are considered risk management Functional requirements: EN ISO 9360-1:2009 Shelf life requirements: 5 years Regulatory requirements: list of standards Production requirements: RCM (risk control measure): requirements of risk management: free of visible particle >100µm/ leakage Transport/shipping/ Packaging requirements Label requirements: inner outer/ IFU: not electronic</p> <p>DWG In4200en 01.00 Design, 2021-10-01 AFO System requirement reviews report, Rev.08, 2021-11-30 Applicable documents: as described above in DD-1 Checklist are approved: System Design, Risk manager Verification leader DDesign and development Plan, ARAs doc no. 1010139, will be up dated constantly. In development phase: Humid 2 plus Luer lock Released by qualification department Mr Schimpf and production: Mathias Ahrens</p> <p>Design input: economical & sustainable reasons: the production of filter and HME will be implemented at the qualified supplier ULAX. This supplier is already manufacturing Humidstar 2+.</p> <p>Purpose and scope: Inhouse and external produced filter at Ulax List of applicable docs: Project Medical filter Inhouse Document Status report ARAs: Including Requirements of - Incl. Clinical evaluation - Chemical analysis - Mechanical drawings - Design and development plan - Usability - List of regulatory requirements: applicable standards, Filter Pus, requirements input; 101067, 2021-02-16, rev. 4 <input type="checkbox"/> E.g. ISO 18562-q:2017 <input type="checkbox"/> IOS 5356-1 <input type="checkbox"/> ISO 80368 <input type="checkbox"/> ISO 9360-2 <input type="checkbox"/> ISO 13328-1</p> <p>- PSUR - List of non conformities - Validation report</p> <p>Materials of device: Drawing: 11066204, rev.02 released 2022-10-14 for Humidstar 2+LL, 2 parts: Part Specification, rev. 03: Humidstar 2+LL MP05840 (included in design transfer): foam MP12054, plastic part 05843 (housing) Supplier decision: part of purchasing process: Medical Filter AirForce ONE Supplier Descison report Gate 6, 2022-10-27</p> <p>Risk management DWAG IN 4210 Risk management: Please see DD-8</p> <p>Kick off meeting: Gate 3.0 review report Medical filter inhouse, reversion 1.0; 2016-04-14, signed 2016-04-22, Including management decision: resources, budget</p> <p>Humidstar 2+LL: screenshot of document management system: justification for start at gate 3: Product is added via scope change to an existing project. Deliverables will be up dated but no Gate Reviews will performed only for this project.</p>

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	<p>Despite this the development route is considered as a new development and all applicable steps had been conducted.</p> <p>-List of regulatory requirements: applicable standards, Filter Pus, requirements input:</p> <p>E.g.</p> <ul style="list-style-type: none"><input type="checkbox"/> ISO 18562-1:2017<input type="checkbox"/> IOS 5356-1<input type="checkbox"/> ISO 80368<input type="checkbox"/> ISO 9360-2<input type="checkbox"/> ISO 13328-1<input type="checkbox"/> ISO 10993 <p>Drawing: 11066204, rev.02 released 2022-10-14 for Humidstar 2+LL, 2 parts:</p> <p>Part Specification, rev. 03: Humidstar 2+LL MP05840 (included in design transfer):</p> <p>foam MP12054,</p> <p>plastic part 05843 (housing)</p> <p>Supplier decision: part of purchasing process:</p> <p>Medical Filter AirForce ONE Supplier Descison report Gate 6, 2022-10-27</p> <p>Risk management DWAG IN 4210, Rev. 03.0, 2023-04-16</p> <p>_A06: Risk Policy and Acceptance Criteria, rev. 03.00:</p> <p>Risk management plan and team are defined.</p> <p>Annex A17 defines the Risk management team: e.g. Product manager, project manager, production expert, Product Quality Manager Clinical engineer</p> <p>Identify hazard, situation, assess and control the risks, is assessed at each gate of D&D, in frame of market monitoring, etc.</p> <p>After gate 8=> transfer to lifecycle management. Risk management is also implemented within the post production review. Depending on product class the PPR will be performed annual or biannual. For Humidstar 2+LL it will be performed biannual.</p> <p>Post market surveillance plan</p> <p>Periodic Safety Update Report,PSUR, 2022-08-01</p> <p>For HME, data evaluated form 04/2020-03/2022, including incidents, trends, scientific search, etc.</p> <p>General conclusion: risk management update not necessary.</p> <p>Risk management plan, AirForce ONE Products, Rev.00, 2022-03-10</p> <p>Archive Design History file</p> <p>RM team: Independent reviewer, clinical expert, Risk manager, CFTM Product Manager, CFTM System engineer, usability expert</p> <p>Risk Assessment table (Hazard analysis for HME), 2022-03-16</p> <p>Contents is predefined:</p> <p>probability is defined with the defined words.</p> <p>Mechanical damage: HME_RM_575 unambiguous numbering of risks: product shall withstand droptest</p> <p>Considerable: HME_RM_1456 Hazard situation due to ignition: IFU shall contain a warning (protective measures are not possible, reason is named</p> <p>Traceability from risk analysis is given to the TSR technical system requirement.</p> <p>TSR technical system requirement</p> <p>Humidstar 2+LL specific risk: HME_RM_421 evaluation of lung gases: IFU shall contain a warning, that device shall be used uncuffed_ residual risk: considerable: benefit risk ratio.</p> <p>3.1.18 Risk related to manufacturing process</p> <p>HME_RM_1135 wrong parts used/ incorrectly supplied goods=> incoming inspection</p> <p>Foam manufacturing: Recticell, Belgium</p> <p>RMR:</p> <p>Air Force One Products Product Risk Management Report, Rev11, 2022-03-23: at the stage of development</p> <p>Clinical benefit: They are universally used of conditioning and filtering of respiratory gases within the limits of the respective devices"</p> <p>Benefit risk Analysis</p> <p>Traceability between verification results and risk controls is provided by TMTA</p> <p>New hazardous situations are included in the risk assessment table</p> <p>Overall residual risk</p> <p>The clinical benefit outweigh the residual risk. Monitoring during life time is assured.</p> <p>TMTA: Traceability Matrix Traceability Analysis), 2023-07-18, linkage of requirements</p> <p>TSR: F-HME_TSR_787: IFU : used only with uncuffed tubes=> input in the IFU checklist</p> <p>IFU Checklist: Test report of requirement 787: AFO Checklist reports, Rev.1 , example: test AFO Checklist IFU</p> <p>Humidstar Plus, including Humidstar 2+LL. Beneath others:F-HME_TSR_787: requirements is passed and accepted.</p> <p>IFU: 9055971, edition 9, 2023-03 HME Humidstar 2+ including Humidstar 2+LL: warning is included.</p> <p>Risk management report will be assessed after each gate. Finally, a risk management process review will be performed by an independent reviewer:</p> <p>AFO RM Process review report, Rev.04, 2023-07-19:</p>

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	<p>RMP had been implemented, all risk considered, control measures evaluated-whether they introduced new hazards or situation, risk are traceable, deficiencies had been reviewed</p> <p>System Validation review report, Rev.00. 2023-08-24 To determine if conducted validation and verification measures were appropriate to demonstrate fulfills the defined requirements, intended use and TSR. Review items all V&V activities fulfilled, no deviation of the checklist=> accepted</p> <p>For the device under review: Australia is not chosen for marketing, if Australia will be chosen, RA will initiate a change request.</p> <p>DWAG IN 4250 clinical evalution, rev.04, 2023-06-26</p> <p>CEP: AirForce ONE Products Clinical Evaluation Plan, Rev.02, 2021-04-22 Filter are considered accessories for medical devices: input documents. MDN 1201</p> <p>Basic UDI: Humidstar 2+LL and Humidstar 2+ identical, but different to the other HMEs Intended use: Heat and moisture exchanger for humidifying respired gases for the patient. (Intended purpose and intended use are considered the same as per MDCG 2022-6.) Patient population: for neonates, with volume of 10-15ml User group: clinical user Claim: per webside : no claim about gas analyses Standards listed. Stages according to MEDDEV 2.7.1 rev4, & MDR Internal and external resources are defined, e.g. Prof. Dr Michael Imhof Clinical performance due to technical specification, literature search required and will be substantiated SOTA. GSPR: defined GSPRs are listed in the new template: DWAG IN 4250 CEP , chapter CER: AirForce ONE Products Clinical Evaluation Report, Rev.02, 2021-07-29 Class IIa, rule 2, STED fie is input for CER Analysis: clear clinical benefit form the use of HME Conclusion: including conclusion from risk management: clinical benefit outweigh overall residual risks PMS process is in place and will be used. Next clinical evaluation is planned no later than 31st of May 2024</p> <p>DMS IN 4230 Design Change Process</p> <p>Not applicable, as reviewed as project was no change project Currently Humidstar 2+LL is marketed only in EU.</p> <p>DCS GM2110 Creation and Change of Material Master Data for Global Portfolio, Version 1.00, 2018-07-31</p> <p>Initial transfer of Humidstar 2 Screenshot of SAP: PRO X Oberfläche: PT OA: PKG-2020-000145 MP05840 HME 2 Plus mit LuerLock Pre tailoring: Luerlock höhe 8.3, in drawing 8.4mm= change of drawing (in stage of Prototype process)</p> <p>Change Package: PKG-2022-003894 Update MP05840 HME 2 Plus mit LuerLock drawing. MP05840= linked with ARAs (program for control of drawing)</p> <p>Data transfer per Mail or via SAP export Humidstar 2+LL launched in August 2023: batch record for tomorrow</p>
Names and titles of persons interviewed	<p>Marcel Clute Simen Carolyn Nonberg (R&A Country Expert) Ann Katrin Hilmer (BA Manager Anästhesie/scribe) Malte Zeuner (Test-Manager) Sebastian Gerlich (Risk Manager ATLAN 2.0) Annalena Brückmann (Testlabor Biocomp) Thomas Schoop (Product Owner BabyLeo) Delia Rähder (Quality Assurance (RC, T)) Ulf Hagedorn (Head of Integrated Management Systems Audit Management) Angela Schober (Clinical Affairs Manager); Tobias Scotti (scribe) (Product Quality Manager - BU Therapy) Schoop (Product Owner Babyleo) Holger Wagner, Head of RA, business unit HCA Sebastian Henning, Product Manager , Filter Dr Janis Vogt, clinical affairs Jan Utmeyer, Skript Luise Lanng, RA, Manager portfolio HCA</p>

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	Alexandra Kreimeyer, Product manager ; Research and development Business Unit HCA Medical Devision Max Hünner, Leaderverification HCA Dr Stefan Schimpf, Head of Product Qualification; Research and development Business Unit HCA Medical Devision, Qualification
Products, components, or projects reviewed	HME filters - Humidstar 2+LL Project ATLAN 2.0 Biocomp ISO 18562 Babyleo TN500 Smart Pilot View
Statement concerning conformity based on objective evidence reviewed for this subsystem	This process is effectively implemented and conforms with requirements

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2.5.6 Design and Development (non-medical Software ISO9001 only)

Subsystem	Design and Development (Non-Medical Device SW , ISO 9001 only)
Audit trail records of	G. Pavlov
Area(s) visited (location, e.g., site visited)	Location # 1 HQ: Moislinger Allee For more details related to Audit location and time refer to chapter 2.2 of this report.
Audit criteria according to audit plan	Only ISO 9001:2015 – Cl 8.3
Brief description of processes or activities evaluated to demonstrate what was audited related to the listed key QMS documents and records reviewed below considering inputs, outputs, and measures	<p><u>Selection of the product / project for assessment</u> SW package <i>Connect Lung Protective Ventilation Analytics – Anesthesia (LPVA)</i> was selected for this audit in line with an audit sampling plan. Additional action items for the audit was to confirm that this SW can be considered as non-medical device</p> <p><u>Evaluation if the sampled Software is a non-medical device</u> Marketing presentation Connected – Lung protective Ventilation Analytics Hospital-data-analytics was demonstrated and assessed during the audit: The software offers following functionality:</p> <ul style="list-style-type: none">- Shows Ventilation Quality indicators to improve the team ventilation performance- Analysis of parameters, ventilation modes and recruitment maneuvers- Enables a consistent implementation of lung protective ventilation practices- Provides benchmarking of Ventilation performance against pre-defined goals <p>The function of demo Software was demonstrated. The data are collected once a day from each connected anesthesia devices, the connection assured via additional Infrastructure software Dräger Gateway, which assures the connectivity of Dräger devices and Dräger SW application devices The data are requested retrospectively from the use case perfume ate pervisu period</p> <p>Ventilation parameters: which are demonstrated are following: VT / IBW, ml / kg PEEP - pressure</p> <p>The results are indicating with red / amber / green indication for the visuals demonstration of not-recommended / possible and recommended parameters areas, while the outcome from the date transfer show the actual statistical evaluation of the past uses of the anesthesia device. The patient data are not transferred and not process by the software.</p> <p>The SW cannot control or impact medical device. The data are collected after the Anastasia session (the Anesthesia medical device shall be in standby after completion of clinical procedure) and therefore does not deliver information which can be and input to immediate use for the handling of the individual patient. Therefore , the auditor concluded that the abovementioned Software is not a Standalone Medical device software and not software with is integrated in Medical device Hardware.</p> <p><u>Design and development process</u> The Software is developed under ISO9001:2015 requirements, according the Software Design Process. Draeger has established the process for Design and development The processes are defined and documented as set of procedures : DWAG IN 4200 is established ad applicable to medical and non-medical devices. The stage -gate is process is defined with 8 stages, whereas first 3 stage-gates form pre-design concepts phase. All design changes are following SOP Design Change Process. Start with Gate 3.0 Preparation ==> 4.0 Definition ==> 4.1 Design ==> 5.0 Realization ==> 6.0 Validation ==> 7.0 CE / Ramp-up / Market Launch ==> 7.1 Serial Production ==> Gate 8.0 Life Cycle/Change</p> <p>At the same time, the designated process DEMF IN6000 is documented design and development of non-medical software: The process DEMF IN6000-en-00 Development of non-medical device software has been developed and laid from May 2023, however was not used during the design and development of LPV software. It also contains the requirements for the changes. The change to the new process is planned to be completed by may 20224</p> <p>In the absence of documented process for non-medical device software, the process IN4200 for MD-Software was partly applied , however according to design and development plan – the DWAG IN4200 : Develop Product was used only to make the plane, the plans however contained the statement that DWAG was only used for the panning stage.</p> <p><u>8.3.2 Design and development planning</u> Design and development plan Rev 3.7 was demonstrated. The roles and resources are defined - the product management teams is demonstrated. The stages are defined as Issue – Iteration. Product release approval</p>

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	<p>For each release, the stages include</p> <ul style="list-style-type: none"> - Planning - Sprint development - Release - Deployment <p><u>8.3.3 Design and development inputs</u> S1000000063642212594 DDB External requirement 2022-08-11 Following defined as design inputs External requirements:</p> <ul style="list-style-type: none"> - Functional and performance requirements - Normative requirement 9001:2015 - Data protection security 2016 /679 - Functional and performance requirements – the - The required verification and validation activities – validation in each sprint is performed as automatic test <p>Backlog – as list of internal requirements</p> <p>Note from the auditor: it was observed that the EN 82304 Health Software is potentially applicable and shall be regarded as mandatory design input. It was explained by Draeger that this standard family is considered in the new edition of the DEMF IN6000, started from V02, and will be applied after implementation of the procedure.- accepted as QMS continuous improvement process</p> <p><u>8.3.4 Design and development controls</u> According to new process, DEMF IN6000 A05 List of implemented Work Items Minimum Content Security requirements demonstrated – documented in DMC -107301 product security whitepaper The stages include Creation of Source Code Verification of Source Code and building Software</p> <p><u>8.3.5 Design and development outputs</u> Building Release Candidate</p> <ul style="list-style-type: none"> - List of implemented Work Items - Product approval - Software Bill of Materials - Approval of the released candidate - approval document was demonstrated <p><u>8.3.6 Design and development changes</u> No particular change process is defined, the changes are understood as repetition of the Sprint cycle</p>
Reviewed documents and records (identification and revision)	<p>Marketing presentation Connected – Lung protective Ventilation Analytics Hospital-data-analytics-cp-DMC-107167-en master Aug 2023 LPV- A Rational for medical device is non-medical device product Ver 0 2023.090 DEMF IN6000 Development of non-medical SW products Ver 00 01.05.2023 DWAG IN4200 : Design Rev. 01.00 IN4200-en-01 design Ver 02 DMC 106527 Lung Protective Ventilation analytics Anesthesia Data Driven solutions Marketing Brochure Design and development plan Rev 3.7 S1000000063642212594 DDB External requirement 2022-08-11 DMC -107301 product security whitepaper The device approval document 2023-04-26</p>
Names and titles of persons interviewed	<p>Room: F05-E1-356 Connect LPV: Fiorian Zichlin – QA/RA René Carolus Product Owner CDA Andreas Weng Head of Tech. & Dev. Global Services Kevin Dornau Director Quality & Regulatory Affairs Business Unit Therapy Markus Hielscher Quality System Manager Auditing Mark Schenk Product Manager Marcel Clute-Simon Head of Product Quality - BU Therapy Leona Schneider (scribe) EHS Manager</p>
Products, components, or projects reviewed	<p>Connect Lung Protective Ventilation Analytics – Anesthesia (LPVA)</p>
Statement concerning conformity based on objective evidence reviewed for this subsystem	<p><input checked="" type="checkbox"/> This process is effectively implemented and conforms to requirements.</p> <p><input type="checkbox"/> Actions are needed for this process to conform to requirements. See audit finding list.</p>

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2.5.7 Production and Service Controls - #10578 (Service Center) / # 90464 (ATLAN Series B23)

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Audit trail records of	Gabriele Mousset
Area(s) visited (location, e.g., site visited)	Location # 10578 (Service Center)/ # 90464 (ATLAN Series B23) For more details related to audit location and time refer to chapter 2.2 of this report.
Audit criteria according to audit plan	ISO 13485:2016, 7.5 ISO 9001 MDR PRODUCTION AND PROCESS CONTROLS Annex IX.2.2d) & e), XI.6.2 Specific Personnel Competency and Training ISO 13485: 6.2 ISO 9001: 7.2, 7.3, 7.5.1 MDR: Annex IX 2.1, 2.2 (a), Article 15, [MPDG §83] MDD: Annex II (3.1, 3.2), Annex V (3.1, 3.2), Annex VI (3.1)
Brief description of processes or activities evaluated to demonstrate what was audited related to the listed key QMS documents and records reviewed below considering inputs, outputs, and measures	<p>Planning of product realization (7.1) <u>PSC1 production planning (GM) 7.1: 7.5.1</u> ///Revalstr. – "Line 2 – ATLAN" /// Production Revalstrasse Anästhesia consists of two pillars: "Linie" and "components". Every ATLAN device will be produced after concrete order of customer have been placed. No stock production of finished devices. Once a month a forecast meeting will be performed and ordering of material and planning of resources will be adjusted. It is verified that the product realization processes are planned, including any necessary controls, controlled conditions, and risk management activities required for the product to meet the specified or intended uses, the statutory and regulatory requirements related to the product. It could be confirmed that the planning of product realization is consistent with the requirements of the other processes of the quality management system and performed in consideration of the quality objectives.</p> <p>USA: <i>Confirm that the organization has determined the applicability of unique device identifier requirements per 21 CFR 801 and 21 CFR 830, has obtained the unique device identifiers from an FDA-accredited UDI-issuing agency, and the required data elements have been entered in the Global Unique Device Identification Database (GUDID) [21 CFR 801, 830].</i> The organization applies UDI identifier which includes Serial number / Batch number to all devices.</p> <p><u>PSC2 Selection of processes (GM) 7.5.1</u> One or more production processes were selected to audit: ///Revalstr. – "Line 2 – ATLAN" /// ATLAN Series have been audited according to audit planning. Reason for the choice have been the change of ATLAN 300/350 from version 1 to version 2. During auditing of "Management" and "Measurement Analysis and Improvement" no observation occurred to change the original plan.</p> <p>Provision of resources (6.1), Infrastructure (6.3) <u>PSC5 infrastructure requirements (GM) 6.3</u> ///Revalstr. – "Line 2 – ATLAN" /// Temperatur /Humidity /Air pressure controls are defined for test places in B23. At each test place sensors are active. The measures will be documented at each test protocol. Furthermore, ESD controls are in place: DEMF SC6700 : Handhabung elektrostatisch gefährdeter Bauteile (ESD) Every person accessing B23 have to be ESD protected. This is clearly marked with colored lines at the entrance. A test station is located at the entrance of the production hall.</p> <p>Brazil: Verify that manufacturing facilities are configured in order to provide adequate means for people flow [RDC ANVISA 16/2013: 5.1.2] Service facilities are configured in order to provide adequate means for people flow and enough space for correct development of the activities. The B23 hall have been audited. Modern building with comfortable space for flow of personnel as well as devices, components and working areas. Lay out plan have been audited as well.</p> <p><u>PSC12 personnel competence (GM) 6.2</u> It have been verified with samples that personnel in service center and audited production area are competent to implement and maintain the processes in accordance with the requirements identified by the medical device organization. ///Service Center - Moisliger Alee/// Roles working in Service center is mainly "Service Mitarbeiter" Furthermore, employees in service center are dedicated to device types and will be trained accordingly. Two employees in Service Center are technicians for ATLAN devices. One sample have been audited. ///Revalstr. – "Line 2 – ATLAN" /// Audited Evidence: Training Evidence Sample Jörg Bentin (Gerätemonteur), Training Evidence Christian Alwert (Gerätemonteur)</p>

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	<p>Work environment and contamination control (6.4)</p> <p><u>PSC4 Product cleanliness (GM) 7.5.2</u></p> <p>Documented requirements for product cleanliness are established. Following aspects are copnsidered and defined in DEMF SC6330 : -Requirements for particle in the air (class 9) -General Cleaning plans exists -pestcontrol It exists a "Reinigingsplan" for B23 with concrete advices for the external personnel. The cleaning execution will be documented from external company in a table. The cleaning results as well as the documentation will be checked and confirmed regularly by responsible leader of production. Futhermore it is defined to control particles according to class 9 requirements. There are 35 measure points in B23 and a limit of 1 Mio parts is defined. The measurement will be evaluated every 3 month.</p> <p><i>Brazil:</i> <i>Confirm that a pest control program has been established and where chemicals are used as part of the pest control program, the company must ensure that they do not affect product quality [RDC ANVISA 16/2013: 5.1.3.4].</i> <i>Verify that themanufacturer has established andmaintains housekeeping procedures and schedules for production areas and warehouses, in conformance with production specifications [RDC ANVISA 16/2013: 5.1.3.1].</i> Pest control in B 23 will be done on a monthly base from external supplier Bockholdt. Last report have been audited.</p> <p><u>PSC6 work environment conditions: training or supervision of personnel (GM) 6.4</u></p> <p>///Revalstr. – "Line 2 – ATLAN "/// It exists a "Reinigingsplan" for B23 with concrete advice for the external personnel. The cleaning will be documented from external company in a table. The cleaning results as well as the documentation will be checked and confirmed regularly by responsible leader of production. Futhermore it is defined to control particles according to class 9. There are 35 measure points and a limit of 1 Mio part is defined. The measurement will be done every 3 month.</p> <p><i>Brazil:</i> <i>Verify that biosafety standards are used, when applicable [RDC ANVISA 16/2013: 5.1.3.6]</i> See description above no further requirements defined and needed</p> <p>Control of production and service provision (7.5.1)</p> <p><u>PSC7/PSC8 validation of processes (GM) 7.5.6</u></p> <p>Generally all processes of ATLAN prodcuton are listed and are validated at least partly. Revalidation will be done according to specific triggers which are defined in SOP e.g. move of production or process changes. The validation of selected ATLAN processes has been done according to IN4300. When steps of validation or process steps haven't been necessary to evaluate, a justification is given. In general IQ/OQ and PQ will be part of the validation process or a justification is given for exclusion of one of these aspects from a dedicated process step validation. No molding no welding or gluing process applicable at ATLAN production. Sample of validation after move of ATLAN production (2020) and Change project (ATLAN 2.0) validation have been audited. Validation demonstrates the ability of the process(es) to consistently achieve the planned result.</p> <p><i>Australia:</i> <i>Confirm that methods of validation have regard to the generally acknowledged state of the art (e.g. current Medical Device Standard Orders - MDSO, ISO/IEC Standards, BP, EP, USP etc.) [TG Act s41CB, TG(MD)R Sch 1 P1 2(1)].</i> Validation of processes are performed according to: GHTF SG3 N99-10 2004 Quality Management Systems-Process Validation, 02.January 2004</p> <p><i>USA:</i> <i>Process validation is required for sterilization, aseptic processing, injection molding, and welding [21 CFR 820.75; preamble comment 143].</i> No sterilization,molding no welding or gluing process applicable at ATLAN production.</p> <p><i>Brazil:</i> <i>Verify that analytical methods, supporting auxiliary systems for production and environmental control that can adversely affect product quality or the quality systemare validated, periodically reviewed and, when necessary, revalidated according to documented procedures [RDC ANVISA 16/2013: 5.5.2, 5.5.3].</i> Temeparture/Humidity and pressure measurement equipment will be calibrated acc. to respective SOP requirements. See also PSC 13/14 with respective samples</p> <p><u>PSC10 monitoring and measuring of product capable to product conformity (GM) 8.2.6</u></p> <p>The system for monitoring and measuring of product characteristics can demonstrate the conformity of products to specified requirements. Test requirements for ATLAN series have been defined. Test specification samples for ATLAN series have been audited. The product risk is considered in the type and extent of product monitoring activities. Risk assessment ATLAN product series is performed and will be adjusted with needed input and output as described under D&D (PMS activities, CAPA handling etc.) Last version of risk assesment ATLAN 2.0 have been audited.</p> <p><u>PSC11 monitoring and measuring of product within specified limits risk conrols GM) 8.2.5</u></p> <p>The processes used in production and service are appropriately controlled, monitored, operated within specified limits and documented in the product realization records. ATLAN Test samples during production have been audited. Risk control measures identified by the manufacturer for production processes are implemented, monitored and evaluated. The product risk is considered in the type and extent of product monitoring activities.</p>

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	<p>Risk assesment ATLAN product series is performed and will be adjusted with needed input/output as described under D&D (PMS activities, CAPA handling etc.) Last version of risk assesment ATLAN 2.0 have been audited. Records of in production- and final tests have been audited.</p> <p><u>PSC15 Validation of software used in production (GM) 7.5.6</u> In production are parts of SAP in usage. Whole SAP tool with all used modules are validated from SW validation officers (see also docu Pavlov). Main used SAP Modul in productionis: PLESS validation protocol have been audited Furthermore some teststations with SW are in use. Here the whole test sttion will be validated. One sample have been audited.</p> <p><u>PSC16 product file (GM) 4.2.3; 7.5.9.1</u> Conduction of product file is defined in: DEMF SC6200 : Produktherstellung ATLAN 300/350 configurations are documented in SAP; based on the customer order specification an individual product test specification is created in SAP which leads to test plans. The individual product file will be completed during production steps up to the final testing in SAP. Each test step can only be processed when the step before has been finished and confirmed in product file. It could be determined within samples that the medical device organization has established and maintained a file for each type of device that includes or refers to the location of device specifications, production process specifications, quality assurance procedures, traceability requirements, and packaging, labelling specifications, and when applicable requirements for installation and servicing. It could also be confirmed via auditing samples of product files that the medical device organization determined the extent of traceability based on the risk posed by the device in the event the device does not meet specified requirements.</p> <p>///Revalstr. – "Line 2 – ATLAN "/// Herstellprotokoll A 350 SN ASSK-0057, Auftragsnummer 62730423, Arbeitsplan all workplaces beginning with workplace1216/ BUM until 750240/ PQMO.</p> <p>USA: <i>If a control number is required for traceability, confirm that such control number is on or accompanies the device throughout distribution [21 CFR 820.120(e)].</i> Every device gets a label with the serial number at the beginning of assembly. Serial No of device is connected to order No and the DHS in .At the end the final label is put on the device which includes also the same serial number. This serial number is also used for the packaging label.</p> <p>Canada: <i>Verify that the manufacturer maintains objective evidence that devices meet the safety and effectiveness requirements of the CMDR [CMDR 9(LA)].</i> <i>Verify that devices sold in Canada have labeling that conforms to Canadian English and French language requirements and contains the manufacturer's name and address, device identifier, control number (for Class III and IV devices), contents of packaging, sterility, expiry, intended use, directions for use and any special storage conditions [CMDR 21-23].</i> <i>Verify that the manufacturer maintains distribution records in respect of a device that will permit a complete and rapid withdrawal of the device from the market [CMDR 52-56].</i> All devices are designed to meet the safety and effectiveness requirements of the CMDR. The type tests (testing of IEC 60601-1 family) are done while design and development phase. The technical documentation is checked while the regular technical file review according to MDR. Additionally, the passed final test (see respective task documentation: "acceptance") makes sure that essential safety aspects are verified. All final labels of the device and packaging contain: manufacturer's name and address, device identifier and any special storage conditions. The language is English, or symbols are used on the label. User manuals in several languages (also French) are available and will be distributed together with device that are sold to Canada. The DHR includes all information about distribution (in case of withdrawal from the market).</p> <p>Brazil: <i>Verify that the manufacturer has established and maintains procedures to ensure integrity and to prevent accidental mixing of labels, instructions, and packaging materials [RDC ANVISA 16/2013: 5.2.2.1].</i> <i>Confirm that the manufacturer has ensured that labels are designed, printed and, where applicable, applied so that they remain legible and attached to the product during processing, storage, handling and use [RDC ANVISA 16/2013: 5.2.2.2].</i> Components (e.g. PCB, Screen) and enclosure have a separate label with their serial number. All these components are documented in the DHR per each device in the ERP System so that accidental mixing is prevented according to DCS GM2150-013. Additionally, scan checks of correct IFU's and labels will be performed. If system gets a wrong scan check the task can't be closed. At the end the final label is put on the device. All final labels are designed and printed that way that they withstand storage, handling and use which is required by IEC 60601-1. The labels are tested according to IEC 60601-1 family.</p> <p>Australia: <i>Verify that the design and location of information to be provided with a medical device, including labelling and instructions for use, comply with Essential Principle 13 and implant cards and leaflets with Essential principle 13A</i> See Canada/Brazil</p> <p><u>PSC17 approve of batch releases GM) 7.5.1; 8.2.6</u> It could be determined that the medical device organization has established and maintained a record of the amount manufactured and approved for distribution. The release will be performed and documented for each medical device (ATLAN series). The record is verified and approved, the device is manufactured according to the file referenced in Task 16, and the requirements for product release were met and documented.</p>

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	<p>///Revalstr. – "Line 2 – ATLAN "/// Following samples have been audited: Herstellprotokoll A 350 SN ASSK-0057, Auftragsnummer 62730423, Herstellerprotokoll A 300 SN ASSK-0001 Auftragsnummer 62727913</p> <p>USA: <i>Verify that labeling is not released for storage or use until a designated individual has examined the labeling for accuracy including, where applicable, the correct unique device identifier (UDI) or Universal Product Code (UPC), expiration date, control number, storage instructions, handling instructions, and any additional processing instructions [21 CFR 820.120(b)].</i> <i>Confirm that labeling is stored in a manner that provides proper identification and prevents mix-ups. Verify labeling and packaging operations are controlled to prevent labeling mix-ups [21 CFR 820.120(c) and (d)].</i> <i>Verify that the label and labeling used for each production unit, lot, or batch are documented in the batch record, as well as any control numbers used [21 CFR 820.120(e), 820.184(e)].</i> The labelling is not released for storage or use until a designated individual has examined the labelling for accuracy including, where applicable, the correct unique device identifier (UDI) or Universal Product Code (UPC), expiration date, control number, storage instructions, handling instructions, and any additional processing instructions Mix up see under PSC 16</p> <p>Brazil: <i>Verify that the device history record of the product includes or refers to the following information: date of manufacture; components used; quantity manufactured; results of inspections and tests; parameters of special processes; quantity released for distribution; labeling; identification of the serial number or batch of production; and final release of the product [RDC ANVISA 16/2013: 3.2.1].</i> <i>Verify that labeling has not been released for storage or use until a designated individual has examined the labeling for accuracy. The approval, including the date, name, and physical or electronic signature of the person responsible, must be documented in the device history record [RDC ANVISA 16/2013: 5.2.2.3].</i> The device history record of the product includes: date of manufacturer; components used; quantity manufactured; results of inspections and tests; parameters of special processes; quantity released for distribution; labelling; identification of the serial number of production and final release of the product. Therefore, it is ensured that labeling has not been released for storage or use until a designated individual has examined the labeling for accuracy. The approval, including the date, name, and physical or electronic signature of the person responsible is documented in the device history record.</p> <p>PSC 18 n/A</p> <p>PSC 19: product status (GM) Product status can be identified by the etiquette documentation. Only products which are finally released can be put into the market.</p> <p>PSC20 - Customer property (GM) ///Service Center - Moisinger Alee/// ATLAN A300 labeled with red sticker found in third level Service Center - Moisinger Alee, label No 3085421308 Customer Property is identified as such with label when received. The reception of devices from customer is managed using the service and maintenance procedure. Every devices in Service center are labeled as such with "Meldungs Nummer" /order no in SAP and colored sticker. The red sticker indicates that cleaning procedure have been finished.</p> <p><u>PSC21 acceptance activities (including supplier) (A) 7.4.3; 8.2.6</u> It have been verified by means of audited samples that acceptance activities assure conformity with specifications and are documented. It have been confirmed based on samples (e.g. leakage testing, pressure tests, electrical safety testing and verifications of individual configurations and accompanying labels and documents) that the extent of acceptance activities is commensurate with the risk posed by the device. ///Revalstr. – "Line 2 – ATLAN "/// 2 samples from ATLAN series have been audited: Herstellprotokoll A 350 SN ASSK-0057, Auftragsnummer 62730423</p> <p>USA: <i>Verify that the manufacturer establishes and maintains procedures to ensure that sampling methods are adequate for their intended use and ensure that when changes occur, the sampling plans are reviewed [21 CFR 820.250(b)].</i></p> <p>Brazil: <i>Verify that sampling plans are defined and based on valid statistical rationale. Each manufacturer must establish and maintain procedures to ensure that sampling methods are suitable for their intended use and are reviewed regularly. A review of sampling plans should consider the occurrence of nonconforming product, quality audit reports, complaints and other indicators [RDC ANVISA 16/2013: 9.2].</i> Acceptance process based on 100% verification, therefore sampling is NA</p> <p>MDR 2017/745 Description of verification and quality assurance techniques at the manufacturing stage including processes and procedures which are to be used (MDR / IVDR Annex IX 2.2 (d) , MDR Annex XI 6.2) Herstellerranweisung ATLAN series have been audited. Description of appropriate tests and trial before / during / after manufacture including frequency and test equipment (MDR / IVDR Annex IX 2.2(e), MDR Annex XI 6.2) Test protocols ATLAN Series have been audited.</p>

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	<p>Control of monitoring and measuring equipment (7.6) <u>PSC13 monitoring and measuring devices needed (GM) 7.6</u></p> <p>The organization has determined the monitoring and measuring devices needed to provide evidence of conformity to specified requirements. Devices are listed in MIMS System. The monitoring and measuring equipment used in production and service control has been identified, adjusted, calibrated and maintained, and is capable of producing valid results. For verification several samples in Service enter and ATLAN production have been audited. Calibration of measurement equipment is performed in specific intervals (usually once a year or after 18 months) Calibration is currently done by "Kalibrierlabor Revalstr." which counts as provider. In some cases devices can be calibrated with other external partners (e.g. Testo) All measuring devices are listed and controlled in MIMS with ID-number, last calibration date, next calibration date, calibration evidence. Responsible persons in Service Center Moisliger Allee and production get once a month an email with status of devices for notification of devices that must be calibrated. Furthermore, each employee of service center is responsible to check calibration status of used devices which is labeled on each device. Calibration certificates are stored and maintained in MIMS Devices are marked with an ID number and the date of the next calibration.</p> <p>Audited Examples : ///Moisliger Allee – "Service center"/// Secu Life PS 300 Patienten Simulator MIMS 302658 (Prüfplatz 107) Tempstecker 37.0 Grad Inventarnummer 302658 ///Revalstr. – "Line 2 – ATLAN" /// Testo 622 (humidity/Temp/pressure) MIMS No 101983, Manometer 6 bar MIMS 10495, Flaschendrucksimulation MB01008 MIMS 302777</p> <p><u>PSC14 monitoring and measuring devices validity of previous measurements in case of non- confirming measurement devices (GM) 7.6</u></p> <p>MDR 2017/745 / IVDR 2017/746</p> <ul style="list-style-type: none">• Test equipment used shall be possible to trace back adequately the calibration of that test equipment. (MDR /IVDR Annex IX_2.2 (e) , MDR Annex XI 6.2) <p>The organization assesses (and records) the validity of previous measurements when equipment is found not to conform to specified requirements, and takes appropriate action on the equipment and any product affected. The control of the monitoring and measuring devices is adequate to ensure valid results. Every device which is processed in "Service Center Moisliger Allee" will be listed in SAP system with incoming date. In SAP the device will be linked to a dedicated work place with ID. Every workspace has a list of measurement equipment used unique at this place. In production all used test equipment will be documented in every test protocol in SAP. It will be possible to trace back every used device with related time-period and related concrete tests and test results. The status of measurement-device at time of usage can be traced back in MIMS. Monitoring and measuring devices are protected from damage or deterioration e.g. via limited access to the "Service Center building Moisliger Allee" and production and the floor where the devices are in usage. Every employee is taught in handling of the measurement equipment. No such event occurred so far. Samples for audited Measurement equipment with related status which have been checked at workplaces and in MIMS find under PSC 13.</p> <p>Customer property (7.5.10) <u>PSC20 customer property (GM) 7.5.10</u> ///Service Center - Moisliger Allee/// ATLAN A300 labeled with red sticker found in third level Service Center - Moisliger Allee, label No 3085421308</p> <p>Customer Property is identified as such with label when received. The reception of devices from customer is managed using the service and maintenance procedure. Every devices in Service center are labeled as such with "Meldungs Nummer" /order no in SAP and colored sticker. The red sticker indicates that cleaning procedure have been finished.</p> <p>Non-conforming product (8.3) <u>PSC22 identification, control, and disposition of nonconforming products is adequate (LA) 8.3</u> ///Revalstr. – "Line 2 – ATLAN" ///</p> <p>There are two areas for storage of non-conforming products. All Non- conforming product is labeled with "Sperraufkleber", edged with red color. The "Sperraufkleber" contains serial no, product code, order no and reason for blocking. In case of Non-conforming product components an additional specific cupboard is used. Samples Non - conforming product handling have been audited: Meldungs No 810000417804 ATLAN A300XL ASSK-0147 ATLAN A300XL ASSK-0147, order No 62728824 N 5 x Sperrlager 1 piece , MK07201 Arbeitsplatz BUM Sperrbereich Order No 62728313,Material No 8609250</p>

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Reviewed documents and records (identification and revision)	<p>Documents</p> <p><u>PSC 4</u> DEMF SC6330 : Instandhaltung und Reinigung DEMF SC6330-de-00 , Rev. 0, requirements for cleaning and pest control</p> <p><u>PSC5</u> DEMF SC6700 : Handhabung elektrostatisch gefährdeter Bauteile (ESD) DEMF-SC6700-de-00.01 , Rev. 00.01 PTS ATLAN 8609010- v 16, Arbeitsbedingungen: Temp 15-35 Grad/Luftdruck: 950-1060/ Luftfeuchte 5%-95%</p> <p><u>PSC 8</u> IN4300 New product introduction en 09.00, defines for process validation.</p> <p><u>PSC 10/PSC11</u> 8609010 Production and Test Specification ATLAN Series, rev 16, Final Test, 3.2.3 and further beginning with leakage etc.... 8621500 Herstelleranweisung ATLAN A350, v21 includes all needed test specification for production.</p> <p><u>PSC/13/14 (GM)</u> DWAG PQ8010 : Betriebsmittelüberwachung DWAG PQ8010-de-02 , Rev. 2</p> <p><u>PSC 12 (GM)</u> DEALL HR3400 : Employee Qualification Process DEALL HR3400-en_de-05.00 , Rev. 05.00</p> <p><u>PSC 15</u> DEALL IT4120 : Validierung qualitätsrelevanter Prozess Software DEALL IT4120-de-02.01 , Rev. 02.01</p> <p><u>PSC16</u> DEMF SC6200 : Produktherstellung DEMF SC6200-de-02 , Rev. 2</p> <p><u>PSC 20 (GM)</u> DEMF SE4300 : Factory Services DEMF SE4300-en-01.00 , Rev. 01.00 , attribute with regulation for customer property and advice for labeling.</p> <p><u>PSC 22</u> DEMF SC6111 : Lenkung von fehlerhaftem Material DEMF-SC6111-de-00.01 , Rev. 00.01 DEMF SC6110 : Behandlung von Abweichungen in der Produktion DEMF-SC6110-de-00.00 , Rev. 00.00</p> <p>Records</p> <p><u>PSC 1</u> Presentation production, 21.09.2023 Organigramm BU Therapie/Anästhesia, Admin Anästhesia Head of production Niko Raap, Teamleader Production (Anja Hidden/Dirk Rowedder/Dirk Sachse) Leader Components (Dirk Sachse) Leader Linie (Anja Hidden) Lay out plan B 23 Anästhesia MDR101-035 3.1. design and Manufacturing information/Flow chart Manufacturing ROFO Chart, 18.09.2023 with forecast planning, upper limit of production 800 pieces, needed pieces per month for profitability 500 pieces. Layout label ATLAN family Sample US ATLAN A 350 UDI 04048675556176 for US only SN ASSA-9998 (Dummy serial No)</p> <p><u>PSC 4/PSC5/PSC6 (GM)</u> Bockholdt pestcontrol last report done on 06.09.2023 report from 12.09.2023, signed, Werk 3 Revalstr. including lay out plans (incl B23) and results, no pests found. Reinigungsplan Gebäude B23, BU Therapie, 2023-07-2023, includes advice for cleaning of B23, weekly and monthly cleanings needed. The execution will be confirmed by personnel and documented in lists. DQS Zertifikat Bockholdt GmbH EN 16636 Zert Nr. 543810 PMS, 08.12.2025 Reinigungsplan B 23 August 2023, filled with confirmation of personnel, 04.03.2023, signed by responsible person in production. Messprotokoll Partikelmessung B23, class 9, 35 measure points, limit 1 Mio, measures on protocol at all points < 25.000 at all measurements points, 13.09.2023 will be repeated every 3 months. Überwachungsplan BU Therapy Perseus/ATLAN_Reiner Bereich, 30.08.2021 Layout label ATLAN family Sample US ATLAN A 350 UDI 04048675556176 for US only SN ASSA-9998 (Dummy serial No) Herstellprotokoll A 350 SN ASSK-0057., Auftragsnummer 62730423, 12.09.2023 Hentschel (Runin Test) Inspect 0010/0020/0030), PP 3.2, measure temp 24 Grad, humidity 71%, humidity 1012 Training Evidence Sample Jörg Bentin (1004324) Gerätemonteur, ESD Training (B70 Prozessstraining) , 27.04 2023</p> <p><u>PSC 7/8</u> Validation master Plan ATLAN 2.0 family, 16.08.2022, v 00 (ARAS transfer, Project Manager Andres Plöger, History: 1.1 ATLAN complete 2019-07-10, 1.2 complete 2019-07-10, 2.1 ATLAN complete 2020-03-05, 2.2 complete 2020-03-05 (complete Validation have been done after move of factory), all defined steps for Change from 1.0 to 2.0 are documented Process FMEA 11232750, v01 Final Assembly, all risks rated in acceptable risk Last Delta Validation MB01987 UNIT RunIN, 11.05.2022</p> <p><u>PSC 10/PSC11</u> Risk assessment table has updated during 2022, Hazard analysis ATLAN 2.0 , 6.22 approved 05.01.2023, Cyber included, typos , some acceptance rationales adjusted. Herstellprotokoll A 350 SN ASSK-0057, Auftragsnummer 62730423, Prüfpunkt 12.1 start of final test Dichtigkeitsprüfung Messwert > 3,72 (ZV02 ZV Air), results ZV021,14/ ZVair0,93, 19.09.2023, Christian Alwert 12. 8(1) Mischertypeneinstellung wird vorgenommen, confirmed with ja,</p>

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	<p>12.08 (9) Leakage and Temp.: Sensor temp test: -4 – +4 Gad / measure -1 Grad, LeakAuto < 100 ml Measurement 10 ml , Leakman spont > 100 ml; measurements 17 ml</p> <p>12. 8(1) Mischertypeneinstellung wird vorgenommen, confirmed with ja,</p> <p>12.08 (9) Leakage and Temp.: Sensor temp test: -4 – +4 Gad / measure -1 Grad, LeakAuto < 100 ml Measurement 10 ml , Leakman spont > 100 ml; measurements 17 ml</p> <p><u>PSC 12</u></p> <p>Training Evidence Sample Jörg Bentin (1004324) Gerätemonteur, ESD Training (B70 Prozesstraining) , 27.04 2023</p> <p>Training Evidence Christian Alwert, 05.03 2019, Training of Final test on A300/350 series</p> <p>Q- Check Christian RAAB ID 1003118, 05.05 2023 incl. evidence for academy training ATLAN A3X0 series.</p> <p>Autorisierungs Freigabe Berechtigung Christian RAAB, ATLAN A3X0 series, signed and approved by employee and team leader on 01.07.2019, 2 parts training : academy and onsite practical advice.</p> <p><u>PSC/13/14 (GM)</u></p> <p>Multimeter Fluke Reg. 33576/3131 AP 113, last calibration 25.09.2022-expiry date 25.09.2023</p> <p>Dräger Prüfstand MIMS No 40281/3132 (manueller Prüfstand) (Prüfplatz 113)</p> <p>Secu Life PS 300 Patienten Simulator MIMS 302658 (Prüfplatz 107)</p> <p>Kalibrierzertifikat, 16.05 2022, Patienten Simulator Nr. 378483-03 next due date 11.2023 Inventarnummer 302658, in System 07.12.2023</p> <p>Kalibrierzertifikat, Nr.315489/2022-06 Inventarnummer 302658 Tempstecker 37.0 Grad, Kalibrierung 07.06.2022, due date 07.12.2023</p> <p>Testo 622 (humidity/Temp/pressure) MIMS No 101983, due date 13.06 2024</p> <p>Kalibrierzertifikat testo MIMS No 101983,pass 16.06.2023.</p> <p>Manometer 6 bar MIMS 10495, due date 02.02.2024</p> <p>Kalibrierzertifikat Dräger, MIMS 10495, 02.02.2022</p> <p>Flaschendrucksimulation MB01008 MIMS 302777, due date 16.02.2024</p> <p>Kalibrierzertifikat Dräger MIMS 302777, 16.02.2023</p> <p><u>PSC 15</u></p> <p>Validation Report PLESS QPS, 2.3 ID 400, approved without further activities 09.05.2023.</p> <p>Validation Report Test station A220001 Ventilation Unit Funktionstest (inkl A180039 SW part v 4.1/1.3.0.0FW 3.x), 25.07.2023, under usage of A 200008 as reference measurement tool, result no observations test results are similar to used equivalence.</p> <p><u>PSC 16</u></p> <p>Herstellprotokoll A 350 SN ASSK-0057, Auftragsnummer 62730423, Arbeitsplan all workplaces beginning with workplace1216/ BUM until 750240/ PQMO.</p> <p><u>PSC17</u></p> <p>Herstellprotokoll A 350 SN ASSK-0057, Auftragsnummer 62730423, Prüfpunkt 12.1 start of final test Dichtigkeitsprüfung</p> <p>Messwert > 3,72 (ZV02 ZV Air), results ZV021,14/ ZVair0,93, 19.09.2023, Christian Alwert</p> <p>12. 8(1) Mischertypeneinstellung wird vorgenommen, confirmed with ja,</p> <p>12.08 (9) Leakage and Temp.: Sensor temp test: -4 – +4 Gad / measure -1 Grad, LeakAuto < 100 ml Mesurement 10 ml , Leakman spont > 100 ml; measurements 17 ml</p> <p>PZAE technical final approval, 19.09.2023 Herr Allwerth</p> <p>Herstellerprotokoll A 300 SN ASSK-0001 Auftragsnummer 62727913, PZAE technical final approval, 08.09.2023. Mathias Junghans.</p> <p><u>PSC20</u></p> <p>ATLAN A300 labeled with red sticker found in third level Service Center - Moisliger Alee, label No 3085421308</p> <p><u>PSC 21</u></p> <p>Herstellprotokoll A 350 SN ASSK-0057, Auftragsnummer 62730423, Prüfpunkt 12.1 start of final test Dichtigkeitsprüfung</p> <p>Messwert > 3,72 (ZV02 ZV Air), results ZV021,14/ ZVair0,93, 19.09.2023, Christian Alwert</p> <p>12. 8(1) Mischertypeneinstellung wird vorgenommen, confirmed with ja,</p> <p>12.08 (9) Leakage and Temp.: Sensor temp test: -4 – +4 Gad / measure -1 Grad, LeakAuto < 100 ml Measurement 10 ml , Leakman spont > 100 ml; measurements 17 ml</p> <p>PZAE technical final approval, 19.09.2023 Herr Allwerth</p> <p>PAB2 Freigabe zur Ablieferung des Produktes, Final test and accompanying documents Torsten Adels, 20.09.2023</p> <p>Herstellerprotokoll A 300 SN ASSK-0001 Auftragsnummer 62727913, PZAE technical final approval, 08.09.2023. Mathias Junghans.</p> <p>PAB2 Freigabe zur Ablieferung des Produktes, Final test and accompanying documents Torsten Adels, 08.09.2023</p> <p>BUM Arbeitsplatz 62729265, SN ASSK-0163, A350, tests finished (Typenschild checked, break tested)</p> <p>Atem System 8609011-06, SN ASRM-3361</p> <p>VM 4 HIT SW used.</p> <p>MB01987 UNIT RunIN- Selbstest valid 21.09 2023 06:21</p> <p>FA 3 Bach Manual mode Label Spanish Version A 621245, test with French not accepted in SAP , Spanish accepted.</p> <p>Sicherheitsbatt Locktite 601 (Glue used in some work places), Juni 2004, storage between 8- 21 degree</p> <p><u>PSC 22</u></p> <p>Meldungs No 810000417804 ATLAN A300XL ASSK-0147, 19.09.2023, Bauteil MK07201 O² Flush Ventil</p> <p>ATLAN A300XL ASSK-0147, order No 62728824, PP 12.2 Dichtigkeitsprüfung 0-27,90 ,measurement -3,33 ml/min, replacement of Bauteil MK07201, retested on 19.09.2023, PP 12.2 pass 0,21 ml/min</p> <p>N 5 x Sperrlager 1 piece , MK07201</p> <p>Arbeitsplatz BUM Sperrbereich Order No 62728313,Material No 8609250 Schubladenschrank, labeled with red sticker, Kratzer seitlich</p>
Names and titles of persons interviewed	<p>Ralf Küster (Indsutrial Engineer, Service center)</p> <p>Martin Lieber (Medical plant Servcie center Moisliger Allee)</p> <p>Herr Hagedorn provides rest of participant names and roles</p>

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Product Service

Subsystem	Production and Service Controls - #10578 (Service Center) / # 90464 (ATLAN Series B23)
Products, components, or projects reviewed	ATLAN Series 300/350 version 2.0
Statement concerning conformity based on objective evidence reviewed for this subsystem	Actions are needed for this process to conform to requirements. See audit findings list

2.5.8 Production and Service Controls - #10578 (Anlauffabrik / Startup Factory)

Subsystem	Production and Service Controls - #10578 (Anlauffabrik/Startup Factory)
Audit trail records of	Martin Szepeannek
Area(s) visited (location, e.g., site visited)	Location # 10578 (Anlauffabrik/startup Factory) For more details related to audit location and time refer to chapter 2.2 of this report.
Audit criteria according to audit plan	<p>"Production and Service Controls: Planning of Production and Service Process (MDSAP Chapter 6, Task 1, Site: 10578); (DIN)(EN) ISO 13485 - 7.1, 7.2.1, 7.5.1 + (DIN)(EN) ISO 9001 - 8.1, 8.2.2, 8.5.1 + MDSAP - Australia - TG(MD)R Sch 1 P1 2, Sch3 P1 C1.4(4), Sch3 P1 C1.1.4(5)(d)&(e) + MDSAP - Brazil - RDC ANVISA 16/2013: 2.2.1, 2.4, 4.1.2, 4.1.7, 5.1 + MDSAP - Japan - MO169: 26, 27, 40 + MDSAP - USA - 21 CFR 801, 820.30(b), 820.20(a), 820.30(h), 820.70(a), 830 + MDR - Article 10.9 ¶3 (g) + MDD - Annex II (3.2), Annex V (3.2)"</p> <p>Production and Service Controls: Selection of Production and Service Process(es) (MDSAP Chapter 6, Task 2, Site: 10578)</p> <p>"Production and Service Controls: Infrastructure (MDSAP Chapter 6, Task 5, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 6.3, 7.5.1 + (DIN)(EN) ISO 9001 - 7.1.3, 7.5.1, 8.5.1 + MDSAP - Brazil - RDC ANVISA 16/2013: 5.1.2, 5.1.5 + MDSAP - Canada - CMDR 14 + MDSAP - Japan - MO169: 6, 24, 40 + MDSAP - USA - 21 CFR 820.70(g), 820.70(f) + MDR - Annex IX.2.2 ¶1"</p> <p>"Production and Service Controls: Work Environment (MDSAP Chapter 6, Task 6, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 6.4 + (DIN)(EN) ISO 9001 - 7.1.4, 7.5.1 + MDSAP - Australia - TG(MD)R Sch1 P2 7.2, 8 + MDSAP - Brazil - RDC ANVISA 16/2013: 5.1.3 + MDSAP - Japan - MO169: 6, 25-1, 25-2; [Old: 6, 25] + MDSAP - USA - 21 CFR 820.70(c), 820.70(d), 820.70(e) + MDR - Annex IX.2.2 ¶1; Annex I (11) + MDD - Annex II (3.2), Annex V (3.2)"</p> <p>"Production and Service Controls: Identification of Processes Subject to Validation (MDSAP Chapter 6, Task 7, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 4.1.6, 7.5.6 + (DIN)(EN) ISO 9001 - 4.4, 7.5.1, 8.4, 8.5.1 + MDSAP - Australia - TG(MD)R Sch1 P2 8.2, 8.3; Sch3 P1 1.4(5)(d) + MDSAP - Brazil - RDC ANVISA 16/2013: 5.5.2, 5.5.3 + MDSAP - Japan - MO169: 6, 5-6, 45; [Old: 6, 45] + MDSAP - USA - 21 CFR 820.75(a) + MDR - Annex IX 2.2 ¶2 (d); Annex XI 6.2 ¶2, 12"</p> <p>"Production and Service Controls: Control, Operation, and Monitoring of the Production and Service Process; Risk Controls (MDSAP Chapter 6, Task 11, Site: 10578); (DIN)(EN) ISO 13485 - 7.1, 7.5.1, 8.1, 8.2.5 + (DIN)(EN) ISO 9001 - 8.1, 8.5.1, 9.1.1 + MDSAP - Australia - TG(MD)R Sch1 P1 2, Sch3 P1 1.4(5)(b)&(e) + MDSAP - Brazil - RDC ANVISA 16/2013: 2.4, 5.1.1, 5.1.6, 8.2, 9.1 + MDSAP - Japan - MO169: 26, 40, 54, 57 + MDSAP - USA - 21 CFR 820.70(a), 820.75(b), 820.250 + MDR - Article 10.9 ¶3 (m); Annex IX 2.2 ¶2 (b2, e); "</p> <p>"Production and Service Controls: Competence of Personnel (MDSAP Chapter 6, Task 12, Site: 10578); (DIN)(EN) ISO 13485 - 6.2 + (DIN)(EN) ISO 9001 - 7.2, 7.3 + MDSAP - Australia - RDC ANVISA 16/2013: 2.3.2 + MDSAP - Japan - MO169: 22 + MDSAP - USA - 21 CFR 820.25, 820.70(d), 820.75(b) + MDR - Annex IX.2.2 ¶1"</p> <p>"Production and Service Controls: Control of Monitoring and Measuring Device (MDSAP Chapter 6, Task 13, Site: 10578); (DIN)(EN) ISO 13485 - 7.5.1, 7.6 + (DIN)(EN) ISO 9001 - 7.1.5, 8.5.1 + MDSAP - Australia - TG(MD)R Sch3 P1 1.4(5)(e) + MDSAP - Brazil - RDC ANVISA 16/2013: 5.1.5, 5.4 + MDSAP - Japan - MO169: 40, 53 + MDSAP - USA - 21 CFR 820.70(g), 820.72 + MDR - Annex IX 2.2 ¶2 (e); Annex XI 6.2 ¶2, 12 ¶1 + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>"Production and Service Controls: Impact Analysis of Monitoring and Measuring Device Found Out of Specifications (MDSAP Chapter 6, Task 14, Site: 10578); (DIN)(EN) ISO 13485 - 7.6 + (DIN)(EN) ISO 9001 - 7.1.5 + MDSAP - Australia - TG(MD)R Sch3 P1 1.4(5)(e) + MDSAP - Brazil - RDC ANVISA 16/2013: 5.4 + MDSAP - Japan - MO169: 53 + MDSAP - USA - 21 CFR 820.72(a) + MDR - Annex IX 2.2 ¶2 (e); Annex XI 6.2 ¶2, 12 ¶1 + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>"Production and Service Controls: Device Master File (MDSAP Chapter 6, Task 16, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 4.2.3, 7.1, 7.5.8, 7.5.9.1 + (DIN)(EN) ISO 9001 - 7.5.1, 8.1, 8.5.2 + MDSAP - Australia - TG(MD)R, Sch1 EP13, Sch3 P1 1.4(5)(c),(d),(e) + 1.9 + MDSAP - Brazil - RDC ANVISA 16/2013: 1.2.26, 2.4, 4.2, 5.2, 6.4 + MDSAP - Canada - CMDR 9(2), 21-23, 52-56, 66-68 + MDSAP - Japan - MO169: 6, 7-2, 26, 47, 48; [Old: 6, 26, 47, 48] + MDSAP - USA - 21 CFR 820.65, 820.120(e), 820.181 + MDR - Article 10.4 ¶1, 10.5, 10.9 ¶3 (b), 10.11, 10.15; Annex IX 2.2 ¶2 (c6); Annex XI 6.1 ¶2 & 12 ¶1 + MDD - Annex II (3.2), Annex VI (3.1)"</p> <p>"Production and Service Controls: Production Record; Evidence of Compliance of Released Devices (MDSAP Chapter 6, Task 17, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 7.5.1, 7.5.8, 7.5.9.1, 8.2.6 + (DIN)(EN) ISO 9001 - 7.5.1, 8.5.1, 8.5.2, 8.6 + MDSAP - Brazil - RDC ANVISA 16/2013: 3.2, 5.2, 6.4 + MDSAP - Japan - MO169: 6, 40, 47, 48, 58, 59 + MDSAP - USA - 21 CFR 820.120, 820.184 + MDR - Article 10.7, 10.9 ¶3 (h); Annex IX 2.2 ¶2 (c7); Annex XI 12 ¶1 + MDD - Annex II (3.2), Annex V (3.2)"</p> <p>"Production and Service Controls: Customer Property (MDSAP Chapter 6, Task 20, Site: 10578); (DIN)(EN) ISO 13485 - 7.5.10 + (DIN)(EN) ISO 9001 - 8.5.3 + MDSAP - Japan - MO169: 51 + MDR - Article 10.9"</p> <p>"Production and Service Controls: Acceptance Activities (MDSAP Chapter 6, Task 21, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 7.4.3, 7.5.8, 8.2.6 + (DIN)(EN) ISO 9001 - 7.5.1, 8.4.2, 8.4.3, 8.5.2, 8.6 + MDSAP - Australia - TG(MD)R Sch1 P1 2, Sch3 P1 C1.1.4(5)(d) + MDSAP - Brazil - RDC ANVISA 16/2013: 5.3.1, 5.3.2, 5.3.3, 5.3.4, 9.2 + MDSAP - Japan - MO169: 6, 39, 47, 58, 59 + MDSAP - USA - 21 CFR 820.80, 820.250(b) + MDR - Article 10.9 ¶3 (m), Annex IX 2.2 ¶2 (b2, e); Annex XI 6.2 ¶2, 12 ¶1 + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>"Production and Service Controls: Identification, Control, and Disposition of Nonconforming Products (MDSAP Chapter 6, Task 22, Site: 10578); (DIN)(EN) ISO 13485 - 7.5.8, 8.3 + (DIN)(EN) ISO 9001 - 8.5.2, 8.7 + MDSAP - Australia - TG(MD)R Sch1 P1 2, Sch3 P1 C1.1.4(5)(b) + MDSAP - Brazil - RDC ANVISA 16/2013: 6.5.1, 6.5.2 + MDSAP - Japan - MO169: 47, 60-1, 60-2, 60-3, 60-4; [Old: 47, 50, 60] + MDSAP - USA - 21 CFR 820.60, 820.90(a), 820.86, 820.100(a) + MDR - Article 10.9 ¶3 (k), 10.12; Annex IX 2.2 ¶2 (b2); Annex XI 6.2 ¶2, 12 ¶1 + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>"Production and Service Controls: Review of Customer Requirements, Distribution Records (MDSAP Chapter 6, Task 25, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 5.2, 7.2.2, 7.5.9 + (DIN)(EN) ISO 9001 - 5.1.2, 7.5.1, 8.2.3, 8.2.4, 8.5.2 + MDSAP - Brazil - RDC ANVISA 16/2013: 6.3 + MDSAP - Canada - CMDR 52-53, 55-56 + MDSAP - Japan - MO169: 6, 11, 28, 48, 49 + MDSAP - USA - 21 CFR 820.160(a) + MDR - Article 10.1"</p> <p>"Production and Service Controls: Installation Activities (MDSAP Chapter 6, Task 26, Site: 10578); (DIN)(EN) ISO 13485 - 7.5.3 + MDSAP - Brazil - RDC ANVISA 16/2013: 8.1 + MDSAP - Japan - MO169: 42 + MDSAP - USA - 21 CFR 820.170 + MDR - Article 10.9 ¶3 (g)"</p> <p>"Production and Service Controls: Servicing Activities (MDSAP Chapter 6, Task 27, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 7.5.4, 8.4 + (DIN)(EN) ISO 9001 - 7.5.1, 9.1.3 + MDSAP - Brazil - RDC ANVISA 16/2013: 8.2 + MDSAP - Japan - MO169: 6, 43, 61 + MDSAP - USA - 21 CFR 820.200 + MDR - Article 10.9 ¶3 (g) + MDD - No specific requirements"</p> <p>"Production and Service Controls: Top Management Commitment to the Production and Service Process (MDSAP Chapter 6, Task 29, Site: 10578); (DIN)(EN) ISO 13485 - 5.1, 5.2 + (DIN)(EN) ISO 9001 - 5.1.1, 5.1.2 + MDSAP - Brazil - RDC ANVISA 16/2013: 2.2.1 + MDSAP - Japan - MO169: 10, 11 + MDR - Article 10.9 ¶3 (c) + MDD - Annex II (2, 3.1)"</p>
Brief description of processes or activities evaluated to demonstrate what was audited related to the listed key QMS documents and records reviewed below considering inputs, outputs, and measures	<p>PSC #1 Planning of production and service process</p> <p>Verified that the product realization processes are planned, including any necessary controls, controlled conditions, and risk management activities required for the product to meet the specified or intended uses, the statutory and regulatory requirements related to the product, and (when applicable) unique device identifier requirements.</p> <p>Confirmed that the planning of product realization is consistent with the requirements of the other processes of the quality management system and performed in consideration of the quality objectives.</p> <p>Andreas Plöger</p> <p>Anlauffabrik/Start-up factory is a production area jointly used by R+D and Production for the assembly of new products from the first integration samples to series production. It provides the complete infrastructure for medical device manufacturing.</p> <p>Development phases:</p> <p>4.0 definition</p> <p>4.1 Design</p> <p>5.0 Realisation</p> <p>6.0 validation</p> <p>7.0 Ramp-Up + Market launch</p> <p>7.1 Serial Production</p> <p>8.0 Stable Installed Base / abschluss New product Intgeration</p> <p>Activities of Ramp-up-Factory range from 5.0 to 7.1 (that menss, it may include production of actually placed on the market devices.</p>

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	<p>900 m² production Space 140m² Albus Production Space NPI – New Product Introduction</p> <p>United States (FDA): Confirmed that the organization has determined the applicability of unique device identifier requirements per 21 CFR 801 and 21 CFR 830, has obtained the unique device identifiers from an FDA-accredited UDI-issuing agency, and the required data elements have been entered in the Global Unique Device Identification Database (GUDID) [21 CFR 801, 830].</p> <p>PSC#2 Selection of production and service process(es) Reviewed production processes considering the following criteria and selected several production processes to audit. Priority criteria for selection: • Use of production processes that directly impact the ability of the device to meet its essential design outputs • New production processes or new product to be introduced in future (Albus Ventilation System (0-Series planned for 2027)).</p> <p>PSC#5 Infrastructure Verified that the organization has determined and documented the infrastructure requirements to achieve product conformity, including buildings, workspace, process equipment, and supporting services. Confirmed that buildings, workspaces, and supporting services allow product to meet requirements. Verified that there are documented and implemented requirements for maintenance of process equipment where important for product quality, and that records of maintenance are maintained.</p> <p>Brazil (ANVISA): Verified that manufacturing facilities are configured in order to provide adequate means for people flow. [RDC ANVISA 16/2013: 5.1.2].</p> <p>PSC#6 Work environment Verified that documented requirements have been established, implemented and maintained for: - health, cleanliness, and clothing of personnel that could have an adverse effect on - product quality - monitoring and controlling work environment conditions that can have an adverse effect on product quality - training or supervision of personnel who are required to work under special environmental conditions - controlling contaminated or potentially contaminated product (including returned products) in order to prevent contamination of other product, the work environment, or personnel.</p> <p>Brazil (ANVISA) No specific Biosafety Standards applicable</p> <p>PSC#7 Identification of processes subject to validation Determined if the selected process(es) and sub-process(es) have been reviewed, including any outsourced processes, to determine if validation of these processes is required. At the stage being, no process validation is required (100% individual end control of finished medical devices).</p> <p>Brazil (ANVISA): n/a</p> <p>United States (FDA): Process validation n/a</p> <p>PSC #10 Monitoring and measurement of product conformity Verified that the system for monitoring and measuring of product characteristics is capable of demonstrating the conformity of products to specified requirements. It could be confirmed that product risk is considered in the type and extent of product monitoring activities.</p> <p>PSC#11 Control, operation, and monitoring of the production and service process; risk controls Verified that the processes used in production and service are appropriately controlled, monitored, operated within specified limits and documented in the product realization records.</p> <p>In addition, verified that risk control measures identified by the manufacturer for production processes are implemented, monitored and evaluated.</p> <p>At time of audit, Integration System iteration 3 is ongoing with 130 devices to be produced; this is made under as realistic production conditions as possible, however, not yet with finally approved components, parts, work instructions and measuring equipment. Produced devices are not yet labelled with a CE mark, however, rest of label is already as realistic as in this development stage possible. All devices manufacture in this stage will stay internally; they are either provided to R+D for further development input, or to Test center for testing; none of these devices is planned or qualified to be placed on the market, all integration systems will be scrapped later.</p> <p>Traceability SAP status ensures that Integration Systems are logistically not able to be placed on the market. This is traced electronically by Revision Index, Serialnumber, material number Material number and revision index must be released in SAP with status "Serial" to be shippable; Serial number also contains date information that would prevent future erroneous release/marketing. Production requirements - Albus Production requirements 11028963 rev.02</p>

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	<p>Produktionskonzept - Albus production Concept 11028978 Rev. 02 Process FMEA 11028980 2023-06-11 Albus NIV Ref. 8430003-05 SN ASSJ-0016 Albus ICU-MID Ref. 8430001-05 SN ASSJ-0016 ➔ Device Status Document (currently in Excel), including Electrical Safety Test values and Final Test Results ➔ Order Card 62728075 from 2023-08-25 Order card contains customer order related specifications (options/variants) and order data. Order card 62728153 Albus NIV 8430003 ➔ ASSJ-0020 PCB 8430381 Release status SAP: Prototype (which is OK for this Pre-Production State) Leakage Current Tester Elabo 300066/3832 next Cal 03/2024 Tsi Flowmeter 20895/5550 nextCal 07/2024</p> <p>PSC#12 Competence of personnel Verified that personnel are competent to implement and maintain the processes in accordance with the requirements identified by the organization.</p> <p>PSC#13 Control of monitoring and measuring device Confirmed that the organization has determined the monitoring and measuring devices needed to provide evidence of conformity to specified requirements. Verified that the monitoring and measuring equipment used in production and service control has been identified, adjusted, calibrated and maintained, and capable of producing valid results. Verified that the control of the monitoring and measuring devices is adequate to ensure valid results. Confirmed that monitoring and measuring devices are protected from damage or deterioration.</p> <p>PSC#14 Impact analysis of monitoring and measuring device found out of specifications Confirmed that the organization assesses (and records) the validity of previous measurements when equipment is found not to conform to specified requirements, and takes appropriate action on the equipment and any product affected. n/a for this process, since devices will not be released for marketing/clinical use</p> <p>PSC#15 Validation of software used for the control of the production and service process Checked if the selected process are software controlled, or if software is used in production equipment or the quality management system. If so Verified that the software is validated for its intended use. Software validation may be part of equipment qualification. Process defines use of Checklist to define if Software is Quality relevant. A QPS Critically assessment is done – QMS software is classified into categories I, II, or III. Based on that, a test specification is created. Criteria for classification are Software Category (non-configured, Configured, customized), Impact of malfunction and Propability of detection. At time of audit, 253 Quality relevant Software Tools are listed in the QPS list, of which 67 are categorized to be Class 3.</p> <p>Screening of Service records for potential events/Complaints has been validated (Tool existing since 2005).</p> <p>PSC#16 Device master file Determined that the manufacturer has established and maintained a file for each type of device that includes or refers to the location of device specifications, production process specifications, quality assurance procedures, traceability requirements, and packaging, labeling specifications, and when applicable requirements for installation and servicing.</p> <p>Confirmed that the manufacturer determined the extent of traceability based on the risk posed by the device in the event the device does not meet specified requirements</p> <p>Produktionsspezifikation PTS 11201373 Draft Version (will be approved to gate 6 or production readiness review). Contains relevant product and variant specific test requirements.</p> <p>Australia (TGA): n/a – not implantable</p> <p>Brazil (ANVISA): Drägerwerk has established and maintains procedures to ensure integrity and to prevent accidental mixing of labels, instructions, and packaging materials. Labels are designed, printed and, where applicable, applied so that they remain legible and attached to the product during processing, storage, handling and use.</p> <p>Canada (HC): Not yet applicable at this stage of Design and Development, since products are not to be released to the market yet.</p> <p>United States (FDA): Not yet applicable at this stage of Design and Development, since products are not to be released to the market yet.</p> <p>PSC#17 Production record; evidence of compliance of released devices Determined that the manufacturer has established and maintained a record of the amount manufactured and approved for distribution for each batch of medical devices, the record is verified and approved, the device is manufactured according to the file referenced in task 16, and the requirements for product release were met and documented.</p> <p>Brazil (ANVISA): Verified that the device history record of the product includes or refers to the following information: date of manufacture; components used; quantity manufactured; results of inspections and tests; parameters of special processes; quantity released for distribution [not yet recorded since devices are not to be released to be marketed]; labeling; identification of the serial number or batch of production; and final release of the product □ all this is recorded and documented already in order to simulate realistic conditions.</p>

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Product Service

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	<p>Not yet all Brazilian labelling handling requirements are not yet implemented within this D+D/Ramp-up project (market release time not before 2027)</p> <p>United States (FDA): Not yet all FDA labelling handling requirements are not yet implemented at this stage of D+D/Ramp-up project (market release time not before 2027).</p> <p>PSC#20 Customer Property n/a for Startup Factory/Anlauffabrik</p> <p>PSC#21 Acceptance activities Verified that acceptance activities assure conformity with specifications and are documented. Confirmed that the extent of acceptance activities i s commensurate with the risk posed by the device.</p> <p>Brazil (ANVISA) & United States (FDA): DEMF PQ8050 : Statistical Techniques DEMF PQ8050 - en_de - 00.00 , Rev. 00.00</p> <p>PSC#22 Identification, control, and disposition of nonconforming products Verified that the identification, control, and disposition of nonconforming products is adequate, based on the risk the nonconformity poses to the device meeting its specified requirements. Drägerwerk ensures that products manufactured in the current state of D+D/Production Ramp-up are not CE marked and therefore can not be released to the market.</p> <p>PSC#25 Review of customer requirements, distribution records Confirmed that the medical device organization performs a review of the customer's requirements, including the purchase order requirements, prior to the medical device organization's commitment to supply a product to a customer. It also was verified that the medical device organization maintains documentation required by regulatory authorities regarding maintenance of distribution records. However, within Startup factory these processes are simulated only (no real customer orders, no distribution of non-CE-marked devices restricted to onsite the facility (Design+Developmen department) only.</p> <p>Brazil (ANVISA): Verified that the manufacturer maintains distribution records which include or make reference to: the name and address of the consignee, the identification and quantity of products shipped, the date of dispatch, and any numerical control used for traceability; However, within Startup factory these processes are simulated only (no real customer orders, no distribution of non-CE-marked devices restricted to onsite the facility (Design+Developmen department) only.</p> <p>Canada (HC): Verified that the manufacturer maintains distribution records that contain sufficient information to permit complete and rapid withdrawal of the medical device from the market; However, within Startup factory these processes are simulated only (no real customer orders, no distribution of non-CE-marked devices restricted to onsite the facility (Design + Development department) only.</p> <p>United States (FDA): Verify that the manufacturer maintains distribution records which include or refer to the location of the name and address of the initial consignee, the identification and quantity of devices shipped; and any control numbers used; However, within Startup factory these processes are simulated only (no real customer orders, no distribution of non-CE-marked devices restricted to onsite the facility (Design + Development department) only.</p> <p>PSC#26 Installation activities Installation and respective verification activities are not applicable to this Product Line (Albus/Anesthesia devices).</p> <p>PSC#27 Servicing activities Servicing activities are not applicable to this Product Line (Albus/Anesthesia devices) in Startup factory.</p> <p>Brazil (ANVISA): Servicing activities are not applicable to this Product Line (Albus/Anesthesia devices) in Startup factory.</p> <p>United States (FDA): Servicing activities are not applicable to this Product Line (Albus/Anesthesia devices) in Startup factory.</p> <p>PSC#29 Top management commitment to the production and service process Based on the assessment of the production process in Startup-Factory overall, it could be determined that management provides the necessary commitment to the production and service control process to ensure devices meet specified requirements and quality objectives.</p>
Reviewed documents and records (identification and revision)	<p>DEMF SE4300 : Factory Services DEMF SE4300 - en - 01.00 , Rev. 01.00</p> <p>DEMF SC6700 : Handhabung elektrostatisch gefährdeter Bauteile (ESD) DEMF - SC6700 - de - 00.01 , Rev. 00.01</p> <p>DWAG IN4300 New Product Introduction Rev. 09:00</p> <p>DWAG IN4320 : Process FMEA / Prozess FMEA DWAG IN4320 - en_de - 08.00 , Rev. 08.00</p> <p>DEALL IT4120 : Validation of Quality Process Software DEALL IT4120 - en - 02.01 , Rev. 02.01</p> <p>DEALL-IT4120_A03-en-02.00 Checklist for Quality Process Software</p> <p>Backup and Archive Plan Template</p> <p>QPS Criticality Assessment.xls</p> <p>Records:</p>

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	<p>Albus Production Project Plan Operations 11028941 Rev. 00 MTN Kalibrierschein Leakage Current Tester Elabo 300066 2023-03-15 Kalbrierschein TSI Flow Meter 20895 2023-07-26 ESD Training Record Assembly Line Colleague Jonas Spahrbier ESD Training Record 2022-07-06 ESD-Unterweisung Jonas Spahrbier (TC Manager correctly shows red flag for extinguish training; however, employee is planned for next upcoming training 2023-10-13; repeated training). Global_Qality_Process_Software_List.xls (ongoing) QPS 219 RI04 Complete ValidationReport for Update of SAP from SAP R/3 to S/4HANA Software Specification QPS_ID219_FSP_Aenderung Langtext und BZW_2.0 Risk analysis and Validation Plan QPS_ID219_RA_Aenderung Langtext und BZW_2.0 Test Specification QPS_ID219_TS_Aenderung Langtext und BZW_2.0 Test Report QPS_ID219_TR_Aenderung Langtext und BZW_2.0 User Trainings CHG0044933_Conversion from from SAP R/3 to S/4HANA (no Trainings, since no functional Changes) QPS ID019 RI09 Complete Validation report "Übersichtsreport für Meldungen"</p>
Names and titles of persons interviewed	<p>Andreas Plöger (Kostenstellenleiter Anlauffabrik/startup Factory) Daniel Sell (Projektmanager NPI) Ulf Hagedorn (scribe) (Head of Integrated Management Systems Audit Management) Tritscher (Systems Engineer) Reimann (Project Manager) Yvonne David (Software Validation Officer + Process Owner IT4120) Michael Blanke (Software Valiation Officer)</p>
Products, components, or projects reviewed	<p>Albus / Anesthesia</p>
Statement concerning conformity based on objective evidence reviewed for this subsystem	<p><input checked="" type="checkbox"/> This process is effectively implemented and conforms to requirements. <input type="checkbox"/> Actions are needed for this process to conform to requirements. See audit finding list.</p>

2.5.9

2.5.10 Production and Service Controls - #90464 (Revalstraße / Ambia)

Subsystem	Production and Service Controls - #90464 (Revalstraße/Ambia)
Audit trail records of	Martin Szepeannek
Area(s) visited (location, e.g., site visited)	Location # 90464 (Revalstraße) For more details related to audit location and time refer to chapter 2.2 of this report.
Audit criteria according to audit plan	<p>"Production and Service Controls: Planning of Production and Service Process (MDSAP Chapter 6, Task 1, Site: 10578); (DIN)(EN) ISO 13485 - 7.1, 7.2.1, 7.5.1 + (DIN)(EN) ISO 9001 - 8.1, 8.2.2, 8.5.1 + MDSAP - Australia - TG(MD)R Sch 1 P1 2, Sch3 P1 C11.4(4), Sch3 P1 C11.4(5)(d)&(e) + MDSAP - Brazil - RDC ANVISA 16/2013: 2.2.1, 2.4, 4.1.2, 4.1.7, 5.1 + MDSAP - Japan - MO169: 26, 27, 40 + MDSAP - USA - 21 CFR 801, 820.30(b), 820.20(a), 820.30(h), 820.70(a), 830 + MDR - Article 10.9 ¶3 (g) + MDD - Annex II (3.2), Annex V (3.2)"</p> <p>Production and Service Controls: Selection of Production and Service Process(es) (MDSAP Chapter 6, Task 2, Site: 10578)</p> <p>"Production and Service Controls: Infrastructure (MDSAP Chapter 6, Task 5, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 6.3, 7.5.1 + (DIN)(EN) ISO 9001 - 7.1.3, 7.5.1, 8.5.1 + MDSAP - Brazil - RDC ANVISA 16/2013: 5.1.2, 5.1.5 + MDSAP - Canada - CMDR 14 + MDSAP - Japan - MO169: 6, 24, 40 + MDSAP - USA - 21 CFR 820.70(g), 820.70(f) + MDR - Annex IX2.2 ¶1"</p> <p>"Production and Service Controls: Work Environment (MDSAP Chapter 6, Task 6, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 6.4 + (DIN)(EN) ISO 9001 - 7.1.4, 7.5.1 + MDSAP - Australia - TG(MD)R Sch1 P2 7.2, 8 + MDSAP - Brazil - RDC ANVISA 16/2013: 5.1.3 + MDSAP - Japan - MO169: 6, 25-1, 25-2; [Old: 6, 25] + MDSAP - USA - 21 CFR 820.70(c), 820.70(d), 820.70(e) + MDR - Annex IX2.2 ¶1; Annex I (11) + MDD - Annex II (3.2), Annex V (3.2)"</p> <p>"Production and Service Controls: Identification of Processes Subject to Validation (MDSAP Chapter 6, Task 7, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 4.1.6, 7.5.6 + (DIN)(EN) ISO 9001 - 4.4, 7.5.1, 8.4, 8.5.1 + MDSAP - Australia - TG(MD)R Sch1 P2 8.2, 8.3; Sch3 P1 1.4(5)(d) + MDSAP - Brazil - RDC ANVISA16/2013: 5.5.2, 5.5.3 + MDSAP - Japan - MO169: 6, 5-6, 45; [Old: 6, 45] + MDSAP - USA - 21 CFR 820.75(a) + MDR - Annex IX 2.2 ¶2 (d); Annex XI 6.2 ¶2, 12"</p> <p>"Production and Service Controls: Monitoring and Measurement of Product Conformity (MDSAP Chapter 6, Task 10, Site: 10578); (DIN)(EN) ISO 13485 - 7.1, 7.5.1, 8.1, 8.2.6 + (DIN)(EN) ISO 9001 - 8.1, 8.5.1, 8.6, 9.1.1 + MDSAP - Australia - TG(MD)R Sch1 P1 2, Sch3 P1 1.4(5)(b)&(e) + MDSAP - Brazil - RDC ANVISA 16/2013: 2.4, 5.1.1, 9.1 + MDSAP - Japan - MO169: 26, 40, 54, 58, 59 + MDSAP - USA - 21 CFR 820.70(a), 820.250(a) + MDR - Article 10.9 ¶3 (m); Annex IX 2.2 ¶2 (b2, e); + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>"Production and Service Controls: Control, Operation, and Monitoring of the Production and Service Process; Risk Controls (MDSAP Chapter 6, Task 11, Site: 10578); (DIN)(EN) ISO 13485 - 7.1, 7.5.1, 8.1, 8.2.5 + (DIN)(EN) ISO 9001 - 8.1, 8.5.1, 9.1.1 + MDSAP - Australia - TG(MD)R Sch1 P1 2, Sch3 P1 1.4(5)(b)&(e) + MDSAP - Brazil - RDC ANVISA 16/2013: 2.4, 5.1.1, 5.1.6, 8.2, 9.1 + MDSAP - Japan - MO169: 26, 40, 54, 57 + MDSAP - USA - 21 CFR 820.70(a), 820.75(b), 820.250 + MDR - Article 10.9 ¶3 (m); Annex IX 2.2 ¶2 (b2, e); "</p> <p>"Production and Service Controls: Competence of Personnel (MDSAP Chapter 6, Task 12, Site: 10578); (DIN)(EN) ISO 13485 - 6.2 + (DIN)(EN) ISO 9001 - 7.2, 7.3 + MDSAP - Australia - RDC ANVISA 16/2013: 2.3.2 + MDSAP - Japan - MO169: 22 + MDSAP - USA - 21 CFR 820.25, 820.70(d), 820.75(b) + MDR - Annex IX2.2 ¶1"</p> <p>"Production and Service Controls: Control of Monitoring and Measuring Device (MDSAP Chapter 6, Task 13, Site: 10578); (DIN)(EN) ISO 13485 - 7.5.1, 7.6 + (DIN)(EN) ISO 9001 - 7.1.5, 8.5.1 + MDSAP - Australia - TG(MD)R Sch3 P1 1.4(5)(e) + MDSAP - Brazil - RDC ANVISA 16/2013: 5.1.5, 5.4 + MDSAP - Japan - MO169: 40, 53 + MDSAP - USA - 21 CFR 820.70(g), 820.72 + MDR - Annex IX 2.2 ¶2 (e); Annex XI 6.2 ¶2, 12 ¶1 + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>"Production and Service Controls: Impact Analysis of Monitoring and Measuring Device Found Out of Specifications (MDSAP Chapter 6, Task 14, Site: 10578); (DIN)(EN) ISO 13485 - 7.6 + (DIN)(EN) ISO 9001 - 7.1.5 + MDSAP - Australia - TG(MD)R Sch3 P1 1.4(5)(e) + MDSAP - Brazil - RDC ANVISA 16/2013: 5.4 + MDSAP - Japan - MO169: 53 + MDSAP - USA - 21 CFR 820.72(a) + MDR - Annex IX 2.2 ¶2 (e); Annex XI 6.2 ¶2, 12 ¶1 + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>"Production and Service Controls: Device Master File (MDSAP Chapter 6, Task 16, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 4.2.3, 7.1, 7.5.8, 7.5.9.1 + (DIN)(EN) ISO 9001 - 7.5.1, 8.1, 8.5.2 + MDSAP - Australia - TG(MD)R, Sch1 EP13, Sch3 P1 1.4(5)(c),(d),(e) + 1.9 + MDSAP - Brazil - RDC ANVISA 16/2013: 1.2.26, 2.4, 4.2, 5.2, 6.4 + MDSAP - Canada - CMDR 9(2), 21-23, 52-56, 66-68 + MDSAP - Japan - MO169: 6, 7-2, 26, 47, 48; [Old: 6, 26, 47, 48] + MDSAP - USA - 21 CFR 820.65, 820.120(e), 820.181 + MDR - Article 10.4 ¶1, 10.5, 10.9 ¶3 (b), 10.11, 10.15; Annex IX 2.2 ¶2 (c6); Annex XI 6.1 ② & 12 ¶1 + MDD - Annex II (3.2), Annex VI (3.1)"</p> <p>"Production and Service Controls: Production Record; Evidence of Compliance of Released Devices (MDSAP Chapter 6, Task 17, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 7.5.1, 7.5.8, 7.5.9.1, 8.2.6 + (DIN)(EN) ISO 9001 - 7.5.1, 8.5.1, 8.5.2, 8.6 + MDSAP - Brazil - RDC ANVISA 16/2013: 3.2, 5.2, 6.4 + MDSAP - Japan - MO169: 6, 40, 47, 48, 58, 59 + MDSAP - USA - 21 CFR 820.120, 820.184 + MDR - Article 10.7, 10.9 ¶3 (h); Annex IX 2.2 ¶2 (c7); Annex XI 12 ¶1 + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>"Production and Service Controls: Acceptance Activities (MDSAP Chapter 6, Task 21, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 7.4.3, 7.5.8, 8.2.6 + (DIN)(EN) ISO 9001 - 7.5.1, 8.4.2, 8.4.3, 8.5.2, 8.6 + MDSAP - Australia - TG(MD)R Sch1 P1 2, Sch3 P1 C11.4(5)(d) + MDSAP - Brazil - RDC ANVISA 16/2013: 5.3.1, 5.3.2, 5.3.3, 5.3.4, 9.2 + MDSAP - Japan - MO169: 6, 39, 47, 58, 59 + MDSAP - USA - 21 CFR 820.80, 820.250(b) + MDR - Article 10.9 ¶3 (m), Annex IX 2.2 ¶2 (b2, e); Annex XI 6.2 ¶2, 12 ¶1 + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>"Production and Service Controls: Identification, Control, and Disposition of Nonconforming Products (MDSAP Chapter 6, Task 22, Site: 10578); (DIN)(EN) ISO 13485 - 7.5.8, 8.3 + (DIN)(EN) ISO 9001 - 8.5.2, 8.7 + MDSAP - Australia - TG(MD)R Sch1 P1 2, Sch3 P1 C11.4(5)(b) + MDSAP - Brazil - RDC ANVISA 16/2013: 6.5.1, 6.5.2 + MDSAP - Japan - MO169: 47, 60-1, 60-2, 60-3, 60-4; [Old: 47, 50, 60] + MDSAP - USA - 21 CFR 820.60, 820.90(a), 820.86, 820.100(a) + MDR - Article 10.9 ¶3 (k), 10.12; Annex IX 2.2 ¶2 (b2); Annex XI 6.2 ¶2, 12 ¶1 + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p>
Brief description of processes or activities evaluated to demonstrate what was audited related to the listed key QMS documents and records reviewed below considering inputs, outputs, and measures	<p>AMBIA Medical Supply Units Manufacturing Line</p> <p>6 Order manager</p> <p>6 Admin for 2 Lines</p> <p>14 HC Technische Klärer (Product Engineering)</p> <p>4 CAD Zeichnerinnen</p> <p>28 Employees Light, Gas management Systems + Components, Arbeitsplatzkomponenten</p> <p>94 Employees Supply Units</p> <p>Pull-Process: Sales defines priorities</p> <p>3D-Tool Part of the Production processes (input)</p> <p>Delivery Reliability is crucial, since most deliveries have to align with Hospital (re)building projects.</p> <p>Medical Supply Units (Production Capacity >10.000 p.a.)</p> <p>Medical Lighting Systems (Production Capacity >6.000 p.a.)</p> <p>Gas Supply Units (Production Capacity >200.000 p.a.)</p> <p>Production Planning Heijunka-Board</p> <p>Durchlaufzeit pro Ambia ca. 6-20 Std.</p> <p>Dräger Interservice is internal and external Logistics Service Provider (Material Supply and shipping)</p> <p>Interservice checks Goods to be shipped for completeness, Drägerwerk checks for Conformity/Merkmalausprägung</p> <p>3D-Planner → Technische Klärung (regulatory, technische Machbarkeit) → Angebot</p> <p>PSC-1 Planning of production and service process</p> <p>Verified that the product realization processes are planned, including any necessary controls, controlled conditions, and risk management activities required for the product to meet the specified or intended uses, the statutory and regulatory requirements related to the product, and (when applicable) unique device identifier requirements.</p> <p>Confirmed that the planning of product realization is consistent with the requirements of the other processes of the quality management system and performed in consideration of the quality objectives.</p> <p>Risk management in production process</p> <p>Risk assessment Table Ambia 11175385 rev. 01</p>

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	<p>Hazardous Situation RM-SUS 4178 Contamination of parts in contact to the gas flow during transport, storage, production, installation and service</p> <p>Risk Control Measures</p> <p>RCM_RM_SUS_4869 Production: gas leading hoses must be packed clean and free from impurity, protected against contamination (Hoses Ends must be sealed)</p> <p>RCM_SUS_4910 Production: Gas hoses shall be visibly checked by an incoming inspection</p> <p>RCM_SUS_5417 Production FMEA shall evaluate the risk of soiling hoses or tubes during production.</p> <p>RCM_SUS_5515 Warnig in Service Instructions "Gas and electrical installations may only be carried out by trained service personnel; Do not allow any contamination (especially oil, grease, or flammable liquids) into the lines or in the terminal unit."</p> <p>United States (FDA):</p> <p>DWAG PQ2140 : International Labeling Requirements - for Medical Devices DWAG PQ2140-en-04.00 , Rev. 04.00</p> <p>DEMFC SC6440: Labeling DEMFC - SC6440 - de - 00 , Rev. 0</p> <p>PSC-2 Selection of production and service process(es)</p> <p>Complete Production has been audited including several processes that directly impact the ability of the device to meet its essential design outputs.</p> <p>PSC-5 Infrastructure</p> <p>Verified that the organization has determined and documented the infrastructure requirements to achieve product conformity, including buildings, workspace, process equipment, and supporting services.</p> <p>Confirmed that buildings, workspaces, and supporting services allow product to meet requirements.</p> <p>Verified that there are documented and implemented requirements for maintenance of process equipment where important for product quality, and that records of maintenance are maintained.</p> <p>Brazil (ANVISA):</p> <p>Verify that manufacturing facilities are configured in order to provide adequate means for people flow.</p> <p>PSC-6 Work environment</p> <p>Verified that documented requirements have been established, implemented and maintained for:</p> <ul style="list-style-type: none">- health, cleanliness, and clothing of personnel that could have an adverse effect on- product quality- monitoring and controlling work environment conditions that can have an adverse effect on product quality- training or supervision of personnel who are required to work under special environmental conditions- controlling contaminated or potentially contaminated product (including returned products) in order to prevent contamination of other product, the work environment, or personnel <p>PTS Chapter 1.1.1 Umweltauflagen:</p> <p>PTS_509: 5°-35°</p> <p>5%-95%</p> <p>950 - 1060hPa</p> <p>These conditions are confirmed during Gas Test</p> <p>Brazil (ANVISA)</p> <p>No specific Biosafety Standards applicable</p> <p>PSC-7 Identification of processes subject to validation</p> <p>Determined if the selected process and sub-process have been reviewed, including any outsourced processes, to determine if validation of these processes is required.</p> <p>Process Validation Report Production Ambia Aras 11044209 Rev. 0.0</p> <p>Attachment 01 to Process Validation Report Production Ambia 1200113578 POS 20 EM 2021-08-19</p> <p>Key Targets of Process Validation have been reached; however, unacceptable PFR (production Failure Rate) has been addressed during Gate 7.0 meeting to be addressed in Product Steering Board. It is also monitored on a daily basis by the Project Engineer and reported weekly into PSB and biweekly into PQB; LCE (Life Cycle Engineering) is responsible for further improvement.</p> <p>Brazil (ANVISA):</p> <p>Verified that analytical methods, supporting auxiliary systems for production and environmental control that can adversely affect product quality or the quality system are validated, periodically reviewed and, when necessary, revalidated according to documented procedures.</p> <p>United States (FDA):</p> <p>Not applicable</p> <p>PSC-10 Monitoring and measurement of product conformity</p> <p>Verified that the system for monitoring and measuring of product characteristics is capable of demonstrating the conformity of products to specified requirements.</p> <p>It could be confirmed that product risk is considered in the type and extent of product monitoring activities.</p> <p>PSC-11 Control, operation, and monitoring of the production and service process; risk controls</p> <p>Verified that the processes used in production and service are appropriately controlled, monitored, operated within specified limits and documented in the product realization records.</p> <p>In addition, verified that risk control measures identified by the manufacturer for production processes are implemented, monitored and evaluated.</p> <p>PSC-12 Competence of personnel</p>

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	<p>Verified that personnel are competent to implement and maintain the processes in accordance with the requirements identified by the organization.</p> <p>PSC-13 Control of monitoring and measuring device Confirmed that the organization has determined the monitoring and measuring devices needed to provide evidence of conformity to specified requirements. Verified that the monitoring and measuring equipment used in production and service control has been identified, adjusted, calibrated and maintained, and capable of producing valid results. Verified that the control of the monitoring and measuring devices is adequate to ensure valid results. Confirmed that monitoring and measuring devices are protected from damage or deterioration.</p> <p>PSC-14 Impact analysis of monitoring and measuring device found out of specifications Confirmed that the organization assesses (and records) the validity of previous measurements when equipment is found not to conform to specified requirements, and takes appropriate action on the equipment and any product affected.</p> <p>Rückmeldebericht RMB417351 2022-08-18: Drehmomentschlüssel 13NM, regg.-Nr. 417351 found out of spec during kcalibration 2022-08-18 (Result: Fail/Pass); Analysis showed, that Product or material approvals are not to be questioned, since Tolerance is higher than measured deviation.</p> <p>PSC-16 Device master file Determined that the manufacturer has established and maintained a file for each type of device that includes or refers to the location of device specifications, production process specifications, quality assurance procedures, traceability requirements, and packaging, labeling specifications, and when applicable requirements for installation and servicing. Confirmed that the manufacturer determined the extent of traceability based on the risk posed by the device in the event the device does not meet specified requirements</p> <p>Australia (TGA): n/a</p> <p>Brazil (ANVISA): Verify that the manufacturer has established and maintains procedures to ensure integrity and to prevent accidental mixing of labels, instructions, and packaging materials. Confirm that the manufacturer has ensured that labels are designed, printed and, where applicable, applied so that they remain legible and attached to the product during processing, storage, handling and use.</p> <p>Canada (HC): Verify that the manufacturer maintains objective evidence that devices meet the safety and effectiveness requirements of the CMDR.</p> <p>United States (FDA): Fertigungsauftrag 62730484 2023-09-11 /2023-09-20 Herstellprotokoll 62730484 2023-09-21, SN ASSJ-0476 Fertigungsauftrag 62730492 2023-09-12 /2023-09-20 Herstellprotokoll 62730492 2023-09-21, SN ASSJ-0484</p> <p>PSC17 Production record; evidence of compliance of released devices Determined if the manufacturer has established and maintained a record of the amount manufactured and approved for distribution for each batch of medical devices, the record is verified and approved, the device is manufactured according to the file referenced in task 16, and the requirements for product release were met and documented. Order Confirmation Kundenauftrag 1200338274 2023-09-01, Customer Dräger Nederland B.V. - Fertigungsauftrag 62730484 2023-09-11 /2023-09-20 - Herstellprotokoll 62730484 2023-09-21, SN ASSJ-0476 - Fertigungsauftrag 62730492 2023-09-12 /2023-09-20 - Herstellprotokoll 62730492 2023-09-21, SN ASSJ-0484</p> <p>Brazil (ANVISA): DWAG PQ2140 : International Labeling Requirements - for Medical Devices DWAG PQ2140 - en - 04.00 , Rev. 04.00</p> <p>United States (FDA): DWAG PQ2140 : International Labeling Requirements - for Medical Devices DWAG PQ2140 - en - 04.00 , Rev. 04.00</p> <p>PSC-21 Acceptance activities Verified that acceptance activities assure conformity with specifications and are documented. Confirmed that the extent of acceptance activities i s commensurate with the risk posed by the device.</p> <p>Brazil (ANVISA): DEMF PQ8050 : Statistical Techniques DEMF PQ8050 - en_de - 00.00 , Rev. 00.00</p> <p>United States (FDA): DEMF PQ8050 : Statistical Techniques DEMF PQ8050 - en_de - 00.00 , Rev. 00.00</p> <p>PSC-22 Identification, control, and disposition of nonconforming products Verified that the identification, control, and disposition of nonconforming products is adequate, based on the risk the nonconformity poses to the device meeting its specified requirements.</p>
Reviewed documents	DEMF SE4300 : Factory Services DEMF SE4300 - en - 01.00 , Rev. 01.00 DEMF SC6700 : Handhabung elektrostatisch gefährdeter Bauteile (ESD) DEMF - SC6700 - de - 00.01 , Rev. 00.01

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and records (identification and revision)	<p>DWAG PQ2140 : International Labeling Requirements - for Medical Devices DWAG PQ2140-en-04.00 , Rev. 04.00</p> <p>DEMF SC6440: Labeling DEMF - SC6440 - de - 00 , Rev. 0</p> <p>DEMF GM2150 : Traceability of products and components DEMF GM2150 - en_de - 03.00 , Rev. 03.00</p> <p>DEMF SC6110 : Behandlung von Abweichungen in der Produktion DEMF - SC6110 - de - 00.00 , Rev. 00.00</p> <p>DEMF SC6120 : Qualitätskennzahlen in der Produktion DEMF - SC6120 - de - 00.00 , Rev. 00.00</p> <p>DEMF SC6130 : Produktionsstopp und Lieferstopp DEMF - SC6130 - de - 00.00 , Rev. 00.00</p> <p>DEMF SC6200 : Produktherstellung DEMF SC6200 - de - 02 , Rev. 2</p> <p>DEMF SC6500 : Dokumentation von Produktionsprozessen DEMF SC6500 - de - 00 , Rev. 0</p> <p>DEMF SC6720 : Schutz vor elektromagnetischen Einflüssen in der Produktion DEMF SC6720 - de - 00 , Rev. 0</p> <p>DWAG IN4203 : Product Verification DWAG IN4203 - en - 02.00 , Rev. 02.00</p> <p>DWAG OF5213 : Produktverpackung DWAG - OF5213 - de - 01 , Rev. 1</p> <p>DWAG PQ2110 : Regulatory Approval to Market Product DWAG PQ2110 - en - 03.00 , Rev. 03.00</p> <p>Records</p> <p>FMEA Schneiden von Schläuchen und Kabeln 11206117 2022-09-14, Pkt. 2.18 Verschließend von Schläuchen mit Endkappen</p> <p>„Grundlegende Sicherheitshinweise“ in Service Connect 1.10 „Umgang mit Sauerstoff und Lachgas“</p> <p>Overview of all FMEAs is kept in PLM Aras</p> <p>BU Work Place Infrastructure OPS Overview PPT</p> <p>Detail Layout House 10 EG</p> <p>Organisation Structure 2023-09-01</p> <p>PRRC Marcus Vorwerk (Product Specific Responsibilities)</p> <p>Tätigkeitsbeschreibung PRRC Vorwerk_Marcus-01_2020.pdf</p> <p>Table of Content Sted File 11173409 rev. 04</p> <p>Product Risk Management Report 111044055 Rev. 09</p> <p>DOC Ambia MDR103-029-2304-002-0 2023-04-27 Rev04</p> <p>Product Test Specification Ambia PTS Electric Components GG53280 Rev.01</p> <p>Marvin Möller, Unterweisung am Arbeitsplatz „Prozessablauf Endmontage“, z.B. 2022-03-02</p> <p>Uwe Golla, Unterweisung am Arbeitsplatz „Prozessablauf Gas- und Elektroprüfung“, z.B. 2022-02-18</p> <p>René Groß, Unterweisung am Arbeitsplatz „Armsysteme“, z.B. 2021-08-18</p> <p>MIMs-Data Base as used and audited in Moislinger Allee</p> <p>MIMS Druckmessgerät 405821, nextCal 2024-11</p> <p>Kalibrierschein Dichtprüfgerät Bremse 405821_20221104_WKSPErev00</p> <p>Order Confirmation Kundenauftrag 1200338274 2023-09-01, Customer Dräger Nederland B.V.</p> <p>Fertigungsauftrag 62730484 2023-09-11 /2023-09-20</p> <p>Herstellprotokoll 62730484 2023-09-21, SN ASSJ-0476</p> <p>Fertigungsauftrag 62730492 2023-09-12 /2023-09-20</p> <p>Herstellprotokoll 62730492 2023-09-21, SN ASSJ-0484</p> <p>IFU Supplement 9052924 Ed. 3</p>
Names and titles of persons interviewed	<p>Marcus Vorwerk (Head of Q&RA sowie Purchasing WPI)</p> <p>Sönke Behrens (PQM für MSS)</p> <p>Benjamin Krüger (Quality Engineer)</p> <p>Joachim Rochel (Director Operations BU WPI)</p> <p>Markus Hielscher (Quality System Manager Auditing)</p> <p>Alexej Agibalow (Regulatory Affairs)</p> <p>Tim Sennholz (Risk Manager)</p> <p>Matthias Brauer (Industrial Engineer)</p> <p>Bastian Stender (Technical Product Manager)</p> <p>Tim Sennholz (remote) (Risk Manager)</p> <p>Heiko Senz (Project Management Operations Business Unit Workplace Infrastructure)</p> <p>David Binder (Scribe) (Product Quality WPI)</p> <p>Marvin Müller (Gerätemonteur)</p>
Products, components, or projects reviewed	<p>AMBIA</p>
Statement concerning conformity based on objective evidence reviewed for this subsystem	<p><input checked="" type="checkbox"/> This process is effectively implemented and conforms to requirements.</p> <p><input type="checkbox"/> Actions are needed for this process to conform to requirements. See audit finding list.</p>

2.5.11 Production and Service Controls - #90464 (Revalstraße / Central Supply Hoses)

Subsystem	Production and Service Controls - #90464 (Revalstraße / Central Supply Hoses)
Audit trail records of	Martin Szepeannek
Area(s) visited (location, e.g., site visited)	Location # 90464 (Revalstraße) For more details related to audit location and time refer to chapter 2.2 of this report.
Audit criteria according to audit plan	<p>"Production and Service Controls: Planning of Production and Service Process (MDSAP Chapter 6, Task 1, Site: 10578); (DIN)(EN) ISO 13485 - 7.1, 7.2.1, 7.5.1 + (DIN)(EN) ISO 9001 - 8.1, 8.2.2, 8.5.1 + MDSAP - Australia - TG(MD)R Sch 1 P1 2, Sch3 P1 C11.4(4), Sch3 P1 C11.4(5)(d)&(e) + MDSAP - Brazil - RDC ANVISA 16/2013: 2.2.1, 2.4, 4.1.2, 4.1.7, 5.1 + MDSAP - Japan - MO169: 26, 27, 40 + MDSAP - USA - 21 CFR 801, 820.30(b), 820.20(a), 820.30(h), 820.70(a), 830 + MDR - Article 10.9 ¶3 (g) + MDD - Annex II (3.2), Annex V (3.2)"</p> <p>Production and Service Controls: Selection of Production and Service Process(es) (MDSAP Chapter 6, Task 2, Site: 10578)</p> <p>"Production and Service Controls: Infrastructure (MDSAP Chapter 6, Task 5, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 6.3, 7.5.1 + (DIN)(EN) ISO 9001 - 7.1.3, 7.5.1, 8.5.1 + MDSAP - Brazil - RDC ANVISA 16/2013: 5.1.2, 5.1.5 + MDSAP - Canada - CMDR 14 + MDSAP - Japan - MO169: 6, 24, 40 + MDSAP - USA - 21 CFR 820.70(g), 820.70(f) + MDR - Annex IX2.2 ¶1"</p> <p>"Production and Service Controls: Work Environment (MDSAP Chapter 6, Task 6, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 6.4 + (DIN)(EN) ISO 9001 - 7.1.4, 7.5.1 + MDSAP - Australia - TG(MD)R Sch1 P2 7.2, 8 + MDSAP - Brazil - RDC ANVISA 16/2013: 5.1.3 + MDSAP - Japan - MO169: 6, 25-1, 25-2; [Old: 6, 25] + MDSAP - USA - 21 CFR 820.70(c), 820.70(d), 820.70(e) + MDR - Annex IX2.2 ¶1; Annex I (11) + MDD - Annex II (3.2), Annex V (3.2)"</p> <p>"Production and Service Controls: Identification of Processes Subject to Validation (MDSAP Chapter 6, Task 7, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 4.1.6, 7.5.6 + (DIN)(EN) ISO 9001 - 4.4, 7.5.1, 8.4, 8.5.1 + MDSAP - Australia - TG(MD)R Sch1 P2 8.2, 8.3; Sch3 P1 1.4(5)(d) + MDSAP - Brazil - RDC ANVISA 16/2013: 5.5.2, 5.5.3 + MDSAP - Japan - MO169: 6, 5-6, 45; [Old: 6, 45] + MDSAP - USA - 21 CFR 820.75(a) + MDR - Annex IX 2.2 ¶2 (d); Annex XI 6.2 ¶2, 12"</p> <p>"Production and Service Controls: Monitoring and Measurement of Product Conformity (MDSAP Chapter 6, Task 10, Site: 10578); (DIN)(EN) ISO 13485 - 7.1, 7.5.1, 8.1, 8.2.6 + (DIN)(EN) ISO 9001 - 8.1, 8.5.1, 8.6, 9.1.1 + MDSAP - Australia - TG(MD)R Sch1 P1 2, Sch3 P1 1.4(5)(b)&(e) + MDSAP - Brazil - RDC ANVISA 16/2013: 2.4, 5.1.1, 9.1 + MDSAP - Japan - MO169: 26, 40, 54, 58, 59 + MDSAP - USA - 21 CFR 820.70(a), 820.250(a) + MDR - Article 10.9 ¶3 (m); Annex IX 2.2 ¶2 (b2, e); + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>"Production and Service Controls: Control, Operation, and Monitoring of the Production and Service Process; Risk Controls (MDSAP Chapter 6, Task 11, Site: 10578); (DIN)(EN) ISO 13485 - 7.1, 7.5.1, 8.1, 8.2.5 + (DIN)(EN) ISO 9001 - 8.1, 8.5.1, 9.1.1 + MDSAP - Australia - TG(MD)R Sch1 P1 2, Sch3 P1 1.4(5)(b)&(e) + MDSAP - Brazil - RDC ANVISA 16/2013: 2.4, 5.1.1, 5.1.6, 8.2, 9.1 + MDSAP - Japan - MO169: 26, 40, 54, 57 + MDSAP - USA - 21 CFR 820.70(a), 820.75(b), 820.250 + MDR - Article 10.9 ¶3 (m); Annex IX 2.2 ¶2 (b2, e); "</p> <p>"Production and Service Controls: Competence of Personnel (MDSAP Chapter 6, Task 12, Site: 10578); (DIN)(EN) ISO 13485 - 6.2 + (DIN)(EN) ISO 9001 - 7.2, 7.3 + MDSAP - Australia - RDC ANVISA 16/2013: 2.3.2 + MDSAP - Japan - MO169: 22 + MDSAP - USA - 21 CFR 820.25, 820.70(d), 820.75(b) + MDR - Annex IX2.2 ¶1"</p> <p>"Production and Service Controls: Control of Monitoring and Measuring Device (MDSAP Chapter 6, Task 13, Site: 10578); (DIN)(EN) ISO 13485 - 7.5.1, 7.6 + (DIN)(EN) ISO 9001 - 7.1.5, 8.5.1 + MDSAP - Australia - TG(MD)R Sch3 P1 1.4(5)(e) + MDSAP - Brazil - RDC ANVISA 16/2013: 5.1.5, 5.4 + MDSAP - Japan - MO169: 40, 53 + MDSAP - USA - 21 CFR 820.70(g), 820.72 + MDR - Annex IX 2.2 ¶2 (e); Annex XI 6.2 ¶2, 12 ¶1 + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>"Production and Service Controls: Impact Analysis of Monitoring and Measuring Device Found Out of Specifications (MDSAP Chapter 6, Task 14, Site: 10578); (DIN)(EN) ISO 13485 - 7.6 + (DIN)(EN) ISO 9001 - 7.1.5 + MDSAP - Australia - TG(MD)R Sch3 P1 1.4(5)(e) + MDSAP - Brazil - RDC ANVISA 16/2013: 5.4 + MDSAP - Japan - MO169: 53 + MDSAP - USA - 21 CFR 820.72(a) + MDR - Annex IX 2.2 ¶2 (e); Annex XI 6.2 ¶2, 12 ¶1 + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>"Production and Service Controls: Device Master File (MDSAP Chapter 6, Task 16, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 4.2.3, 7.1, 7.5.8, 7.5.9.1 + (DIN)(EN) ISO 9001 - 7.5.1, 8.1, 8.5.2 + MDSAP - Australia - TG(MD)R, Sch1 EP13, Sch3 P1 1.4(5)(c),(d),(e) & 1.9 + MDSAP - Brazil - RDC ANVISA 16/2013: 1.2.26, 2.4, 4.2, 5.2, 6.4 + MDSAP - Canada - CMDR 9(2), 21-23, 52-56, 66-68 + MDSAP - Japan - MO169: 6, 7-2, 26, 47, 48; [Old: 6, 26, 47, 48] + MDSAP - USA - 21 CFR 820.65, 820.120(e), 820.181 + MDR - Article 10.4 ¶1, 10.5, 10.9 ¶3 (b), 10.11, 10.15; Annex IX 2.2 ¶2 (c6); Annex XI 6.1 ② & 12 ¶1 + MDD - Annex II (3.2), Annex VI (3.1)"</p> <p>"Production and Service Controls: Production Record; Evidence of Compliance of Released Devices (MDSAP Chapter 6, Task 17, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 7.5.1, 7.5.8, 7.5.9.1, 8.2.6 + (DIN)(EN) ISO 9001 - 7.5.1, 8.5.1, 8.5.2, 8.6 + MDSAP - Brazil - RDC ANVISA 16/2013: 3.2, 5.2, 6.4 + MDSAP - Japan - MO169: 6, 40, 47, 48, 58, 59 + MDSAP - USA - 21 CFR 820.120, 820.184 + MDR - Article 10.7, 10.9 ¶3 (h); Annex IX 2.2 ¶2 (c7); Annex XI 12 ¶1 + MDD - Annex II (3.2), Annex V (3.2)"</p> <p>"Production and Service Controls: Acceptance Activities (MDSAP Chapter 6, Task 21, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 7.4.3, 7.5.8, 8.2.6 + (DIN)(EN) ISO 9001 - 7.5.1, 8.4.2, 8.4.3, 8.5.2, 8.6 + MDSAP - Australia - TG(MD)R Sch1 P1 2, Sch3 P1 C11.4(5)(d) + MDSAP - Brazil - RDC ANVISA 16/2013: 5.3.1, 5.3.2, 5.3.3, 5.3.4, 9.2 + MDSAP - Japan - MO169: 6, 39, 47, 58, 59 + MDSAP - USA - 21 CFR 820.80, 820.250(b) + MDR - Article 10.9 ¶3 (m), Annex IX 2.2 ¶2 (b2, e); Annex XI 6.2 ¶2, 12 ¶1 + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>"Production and Service Controls: Identification, Control, and Disposition of Nonconforming Products (MDSAP Chapter 6, Task 22, Site: 10578); (DIN)(EN) ISO 13485 - 7.5.8, 8.3 + (DIN)(EN) ISO 9001 - 8.5.2, 8.7 + MDSAP - Australia - TG(MD)R Sch1 P1 2, Sch3 P1 C11.4(5)(b) + MDSAP - Brazil - RDC ANVISA 16/2013: 6.5.1, 6.5.2 + MDSAP - Japan - MO169: 47, 60-1, 60-2, 60-3, 60-4; [Old: 47, 50, 60] + MDSAP - USA - 21 CFR 820.60, 820.90(a), 820.86, 820.100(a) + MDR - Article 10.9 ¶3 (k), 10.12; Annex IX 2.2 ¶2 (b2); Annex XI 6.2 ¶2, 12 ¶1 + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p>
Brief description of processes or activities evaluated to demonstrate what was audited related to the listed key QMS documents and records reviewed below considering inputs, outputs, and measures	<p>21 Employees in Production for Kits and accessories BU Therapy as Manufacturer within DRÄGER Medical BU HCA as marketing organisation</p> <p>PSC-1 Planning of production and service process Verified that the product realization processes are planned, including any necessary controls, controlled conditions, and risk management activities required for the product to meet the specified or intended uses, the statutory and regulatory requirements related to the product, and (when applicable) unique device identifier requirements. Confirmed that the planning of product realization is consistent with the requirements of the other processes of the quality management system and performed in consideration of the quality objectives.</p> <p>Risk management in production process</p> <p>United States (FDA): DWAG PQ2140 : International Labeling Requirements - for Medical Devices DWAG PQ2140-en-04.00 , Rev. 04.00 DEMF SC6440: Labeling DEMF - SC6440 - de - 00 , Rev. 0</p> <p>PSC-2 Selection of production and service process(es) Complete Production has been audited including several processes that directly impact the ability of the device to meet its essential design outputs.</p> <p>PSC-5 Infrastructure Verified that the organization has determined and documented the infrastructure requirements to achieve product conformity, including buildings, workspace, process equipment, and supporting services. Confirmed that buildings, workspaces, and supporting services allow product to meet requirements. Verified that there are documented and implemented requirements for maintenance of process equipment where important for product quality, and that records of maintenance are maintained.</p> <p>Brazil (ANVISA):</p>

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	<p>Verify that manufacturing facilities are configured in order to provide adequate means for people flow.</p> <p>PSC-6 Work environment Verified that documented requirements have been established, implemented and maintained for:</p> <ul style="list-style-type: none">- health, cleanliness, and clothing of personnel that could have an adverse effect on- product quality- monitoring and controlling work environment conditions that can have an adverse effect on product quality- training or supervision of personnel who are required to work under special environmental conditions- controlling contaminated or potentially contaminated product (including returned products) in order to prevent contamination of other product, the work environment, or personnel <p>Brazil (ANVISA) No specific Biosafety Standards applicable</p> <p>PSC-7 Identification of processes subject to validation Determined if the selected process and sub-process have been reviewed, including any outsourced processes, to determine if validation of these processes is required.</p> <p>Brazil (ANVISA): Verified that analytical methods, supporting auxiliary systems for production and environmental control that can adversely affect product quality or the quality system are validated, periodically reviewed and, when necessary, revalidated according to documented procedures.</p> <p>United States (FDA): Not applicable</p> <p>PSC-10 Monitoring and measurement of product conformity Verified that the system for monitoring and measuring of product characteristics is capable of demonstrating the conformity of products to specified requirements. It could be confirmed that product risk is considered in the type and extent of product monitoring activities.</p> <p>Raumedic Gas Supply Hose Air 200m 5000782 (no Caps) 14bar-Test Formblatt Weekly Prüfanweisung/Prüfplan 8608533 2016-10-13 Filled Form Weekly 14bar-Test Prüfplan for Hose Sample M36011 3m 2023-09-18 Defines a weekly 14bar test, however, test equipment is neither specified nor recorded. Measurement-/Test Equipment not documented in record - see Findings List internal Calibration</p> <p>FMEA/Risk analysis CS Hoses Risik assesemnt V2.3 2023-07-04 Production Risk Control measure: CS_RM-566 The product shall be delivered Clean but not sterile CS-TSR-432 The Product shall not have a level of hydrocarbon greater than 550mg/spm and be free from particles acc. To ISO15001 Verification report CS_TRS_156_TR3 Test report 14-00128-PR-004 rev. 0 ➔ Test Result: Particle measureent, Oils Content, Ignition temperature passed.</p> <p>PSC-11 Control, operation, and monitoring of the production and service process; risk controls Verified that the processes used in production and service are appropriately controlled, monitored, operated within specified limits and documented in the product realization records. In addition, verified that risk control measures identified by the manufacturer for production processes are implemented, monitored and evaluated.</p> <p>PSC-12 Competence of personnel Verified that personnel are competent to implement and maintain the processes in accordance with the requirements identified by the organization.</p> <p>PSC-13 Control of monitoring and measuring device Confirmed that the organization has determined the monitoring and measuring devices needed to provide evidence of conformity to specified requirements. Verified that the monitoring and measuring equipment used in production and service control has been identified, adjusted, calibrated and maintained, and capable of producing valid results. Verified that the control of the monitoring and measuring devices is adequate to ensure valid results. Confirmed that monitoring and measuring devices are protected from damage or deterioration.</p> <p>PSC-14 Impact analysis of monitoring and measuring device found out of specifications Confirmed that the organization assesses (and records) the validity of previous measurements when equipment is found not to conform to specified requirements, and takes appropriate action on the equipment and any product affected.</p> <p>PSC-16 Device master file Determined that the manufacturer has established and maintained a file for each type of device that includes or refers to the location of device specifications, production process specifications, quality assurance procedures, traceability requirements, and packaging, labeling specifications, and when applicable requirements for installation and servicing. Confirmed that the manufacturer determined the extent of traceability based on the risk posed by the device in the event the device does not meet specified requirements</p> <p>Australia (TGA): n/a</p>

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	<p>Brazil (ANVISA): Verify that the manufacturer has established and maintains procedures to ensure integrity and to prevent accidental mixing of labels, instructions, and packaging materials. Confirm that the manufacturer has ensured that labels are designed, printed and, where applicable, applied so that they remain legible and attached to the product during processing, storage, handling and use.</p> <p>Canada (HC): Verify that the manufacturer maintains objective evidence that devices meet the safety and effectiveness requirements of the CMDR.</p> <p>PSC17 Production record; evidence of compliance of released devices Determined if the manufacturer has established and maintained a record of the amount manufactured and approved for distribution for each batch of medical devices, the record is verified and approved, the device is manufactured according to the file referenced in task 16, and the requirements for product release were met and documented.</p> <p>Brazil (ANVISA): DWAG PQ2140 : International Labeling Requirements - for Medical Devices DWAG PQ2140 - en - 04.00 , Rev. 04.00</p> <p>United States (FDA): DWAG PQ2140 : International Labeling Requirements - for Medical Devices DWAG PQ2140 - en - 04.00 , Rev. 04.00</p> <p>PSC-21 Acceptance activities Verified that acceptance activities assure conformity with specifications and are documented. Confirmed that the extent of acceptance activities is commensurate with the risk posed by the device.</p> <p>Brazil (ANVISA): DEMF PQ8050 : Statistical Techniques DEMF PQ8050 - en_de - 00.00 , Rev. 00.00</p> <p>United States (FDA): DEMF PQ8050 : Statistical Techniques DEMF PQ8050 - en_de - 00.00 , Rev. 00.00</p> <p>PSC-22 Identification, control, and disposition of nonconforming products</p>
Reviewed documents and records (identification and revision)	<p>DEMF SE4300 : Factory Services DEMF SE4300 - en - 01.00 , Rev. 01.00 DWAG PQ2140 : International Labeling Requirements - for Medical Devices DWAG PQ2140-en-04.00 , Rev. 04.00 DEMF SC6440: Labeling DEMF - SC6440 - de - 00 , Rev. 0 DEMF GM2150 : Traceability of products and components DEMF GM2150 - en_de - 03.00 , Rev. 03.00 DEMF SC6110 : Behandlung von Abweichungen in der Produktion DEMF - SC6110 - de - 00.00 , Rev. 00.00 DEMF SC6120 : Qualitätskennzahlen in der Produktion DEMF - SC6120 - de - 00.00 , Rev. 00.00 DEMF SC6130 : Produktionsstopp und Lieferstopp DEMF - SC6130 - de - 00.00 , Rev. 00.00 DEMF SC6200 : Produktherstellung DEMF SC6200 - de - 02 , Rev. 2 DEMF SC6500 : Dokumentation von Produktionsprozessen DEMF SC6500 - de - 00 , Rev. 0 DWAG OF5213 : Produktverpackung DWAG - OF5213 - de - 01 , Rev. 1 DWAG PQ2110 : Regulatory Approval to Market Product DWAG PQ2110 - en - 03.00 , Rev. 03.00</p> <p>Records: Raumedic Gas Supply Hose Air 200m 5000782 (no Caps) 14bar-Test Formblatt Weekly Prüfanweisung/Prüfplan 8608533 2016-10-13 Filled Form Weekly 14bar-Test Prüfplan for Hose Sample M36011 3m 2023-09-18 PTS 8608533 ZV-Schläuche Rev. 03 Hardcopy IFU 9053929 Ed. 6 2021-02 in Production Lagerzugangsschein zu Fertigungsauftrag 65580704 Wartungsprotokoll der Produktlinie ZV-Schläuche 2023 (hardcopy record template signed 2022-12-22, filled) Weekly measurement length angles table week 38 Calibration Certificate MIMS 412258/3808 FC0750 Leak Detector nextCal 2024-09 412258_20230915_WKSPErev00 internal Calibration 03_1801_MB01593_Kalibrieranforderungen MB01593</p> <p>Kalibrierprotokoll MIMS Grenzlehre 4222340 ID 331773/2023-09-14 MTN Calibration Services, including assessment of Calibration Certificate and signature (2023-09-19) gemäß Calibration Routine KA MB01593 Rev. 02 from2019-09-10</p> <p>Non-conforming Product example 3 Examples 08/2023 09/2023 Fertigungsbegleitende Qualitätsmeldungen 810000410409 (for 5002096, Winkelstecker, Oberfläche beschädigt), with reference to Fertigungsauftrag (65557194, M36011; Air-ZV-Schlauch) 810000412481 (for 2002085 Stecker, kauttes Gewinde) with reference to Fertigungsauftrag (65357, M36020 Air-ZV-Schlauch) 810000412456 (for M36772 Aufkleber verklebt, unansehnlich)) with reference to Fertigungsauftrag (65565331, M36026, Air-ZV-Schlauch)</p> <p>FMEA/Risk nalysis</p>

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	CS Hoses Risik assesemnt V2.3 2023-07-04 Production Risk Control measure: CS_RM-566 The product shall be delivered Clean but not sterile CS-TSR-432 The Product shall not have a level of hydrocarbon greater than 550mg/spm and be free from particles acc. To ISO15001 Verification report CS_TRS_156_TR3 Test report 14-00128-PR-004 rev. 0 <input type="checkbox"/> Test Result: Particle measureent, Oils Content, Ignition temperature passed.
Names and titles of persons interviewed	Dirk Geisteier (Head of Production Line Respiratory Care/ Warming Therapy) Frank Wehde (Teamleiter Monitoring & IT, Kits and Accessories) Hannes Fabig (Quality Engineer - BU Therapy) Andreas Maresch (Industrial Engineer / Pre-installation Manager Monitoring & IT, Kits and Accessories) Alexandre Barette (Product Quality Manager) Jochen Meyn (Quality Manager Operations - BU Therapy) Alexander Kühn (Industrial Engineer) Andre Möller (Quality Engineer) Tony Vertein (Toby Vertein Entw. OPT) Axel Bürger (Industrial Engineer) Markus Hielscher (scribe) (Quality System Manager Auditing)
Products, components, or projects reviewed	Central Supply Hoses
Statement concerning conformity based on objective evidence reviewed for this subsystem	<input checked="" type="checkbox"/> Actions are needed for this process to conform to requirements. See audit finding list.

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2.5.12 Production and Service Controls - #10578 (Moislinger Allee / Service Center)

Subsystem	Production and Service Controls - #10578 (Service Center)
Audit trail records of	Honorata Donnermaier
Area(s) visited (location, e.g., site visited)	Location #10578 (Moislinger Allee) For more details related to audit location and time refer to chapter 2.2 of this report.
Audit criteria according to audit plan	MDSAP Tasks: #1-3, #5-7, #9, #18, #19-20, #24-#26, #28-#29 ISO 13485:2016, 7.5 ISO 9001 MDR PRODUCTION AND PROCESS CONTROLS Annex IX.2.2d) & e), XI.6.2
Brief description of processes or activities evaluated to demonstrate what was audited related to the listed key QMS documents and records reviewed below considering inputs, outputs, and measures	<p>SC1 - Planning of production and service process</p> <p>///Service Centre - Moislinger Allee/// (HD) Global Service Centre Lübeck is responsible for performing repairs on the devices, approx. 65 employees in the Service Centre in Lübeck are working of Medical Devices. There are three groups, dosage & Sensors, Intensive Care & WPI and Spare Parts. Last year approx. 9200 orders regarding medical devices were received.</p> <p>The activities that are performed in the service center include:</p> <ul style="list-style-type: none">- Maintenance.- Repair.- Investigation.- Calibration.- Upgrade. <p>The service orders planning is done via SAP, each construction group has a specific target date for repairs. The order is assigned to technicians based on availability. The principle of first come first serve is applied. This planning process was demonstrated in SAP during the audit (Workplace/ capacities/ formula constant).</p> <p>Service process is monitored and reported on monthly base including service KPIs. The one of the top devices by services are M540 patient monitor and Vapor 2000 anesthetic evaporates.</p> <p>Logistic center C45 and IS4 inbound, outbound, storage, packaging (HD) For the warehouse following applicable processes were identified: preservation, traceability, incoming inspection and infrastructure including Pest control. Those processes are established and implemented.</p> <p>US The organisation applies UDI identifier and Serial number / Batch number to all devices.</p> <p>PSC 2 - Selection of production and service process(es) ///Service Centre - Moislinger Allee/// (HD) The service process was selected to audit. The criticality of the process is considered as the part of the process is outsource to the external supplier. The initial cleaning and disinfection of the devices sent for service are outsourced. The service order of Perseus A500 class IIb (Prüfkarte 308450914) was selected.</p> <p>Logistic center C45 and S4 inbound, outbound, storage, packaging (HD) Logistics centrum / warehouse - the area included the material supply, Incoming inspection area, vertical automated storage / Commissioning of the parts and components for all production lines. NLZ – material warehouse / commissioning for production. ES4 – distribution centrum ES4</p> <p>PSC 3 - Controls for the implementation of selected production and service process(es) Logistic center C45 and S4 inbound, outbound, storage, packaging (HD) It has been verified by the auditor that logistic process follows defined procedures and SOPs.</p> <p>PSC 4 - ///Service Centre - Moislinger Allee/// (HD) There are no specific requirements for the cleanliness in the repair centre. The general hygiene plan PQ 8830 is applicable. The most important standard for repair centre infrastructure is an ESD procedure, this applies to all areas in which the electrostatically sensitive components, assemblies or product are unprotected.</p> <p>Brazil: Pest control in B 23 will be done on a monthly base from external supplier Bockholdt. Last report have been audited.</p> <p>PSC 5 - Infrastructure ///Service Center - Moislinger Allee/// (HD) Requirements for ESD were taken as an example in the Service Center. The maintenance of the workplaces is done based on a documented procedure. There is a regular monitoring of the values in the workstations, if there are some deficiencies found, measures should be taken. As demonstrated for the workplace MAZ 3OG.</p> <p>Logistic center C45 and S4 inbound, outbound, storage, packaging (HD)</p>

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	<p>The process is defined according to SOP DEMF SC6330 Instandhaltung und Reinigung. Cleaning is performed on the regular basis by external supplier. During the audit in the warehouse / logistics it was observed that all structures are very clean. There are no areas sensitive to cleaning impact and no areas with special requirements for cleanliness.</p> <p>It was verified that the pest traps are in place in indicated on the Pest control plan (Traps 77 and 78 opposite to the commissioning area), the fly traps are located near large goods doors. Pest control is outsourced to An Bockholdt a service agreement is in place. The plan and protocol were demonstrated during the audit ref to document at records section.</p> <p>Temperature and humidity are monitored, and records are provided on monthly base. There are 4 temperature sensors installed west, east, south and north.</p> <p>Additional country-specific requirements: Brazil The facility is configured in order to provide adequate means for people flow and enough space for the manufacturing activities to be performed. Work spaces are identified and provided with the necessary tools for the production step to be performed. Confirmed by observation during the audit Service facilities are configured in order to provide adequate means for people flow and enough space for correct development of the activities.</p> <p>PSC6 - Work environment conditions; training or supervision of personnel (HD) It exists a "Reinigungsplan" for B23 with concrete advice for the external personnel. The cleaning will be documented from external company in a table. The cleaning results as well as the documentation will be checked and confirmed regularly by responsible leader of production. Furthermore it is defined to control particles according to class 9. There are 35 measure points and a limit of 1 Mio part is defined. The measurement will be done every 3 month.</p> <p>Brazil: See description above no further requirements defined and needed</p> <p>Control of production and service provision (7.5.1)</p> <p>PSC7/PSC8 - Validation of processes (HD) no validation for process in service area.</p> <p>Australia / USA / Brazil: No sterilization,molding no welding or gluing process applicable.</p> <p>PSC 9 - Validation of sterilization process (HD) Logistic center C45 and S4 inbound, outbound, storage, packaging (HD) According to the information from Head of Production supply there are no materials delivered in sterile conditions.</p> <p>PSC 10 - Monitoring and measurement of product conformity (HD) Product conformity is monitored and measured during in process controls. Test methods, test plan and test records were available, verified by the etiquette documentation.</p> <p>PSC 11 - Control, operation, and monitoring of the production and service process; risk controls ///Service Center - Moisliger Alee/// (HD) Service activities are documented in SAP and accompanied from test protocols which are link to the order.</p> <p>Australia Risk control measures exist, see risk management.</p> <p>PSC12 - Personnel competence (GM) It have been verified with samples that personnel in service center and audited production area are competent to implement and maintain the processes in accordance with the requirements identified by the medical device organization. ///Service Center - Moisliger Alee/// Roles working in Service center is mainly "Service Mitarbeiter" Furthermore, employees in service center are dedicated to device types and will be trained accordingly. Two employees in Service Center are technicians for ATLAN devices. One sample have been audited.</p> <p>PSC13 - Monitoring and measuring devices needed (GM) The organization has determined the monitoring and measuring devices needed to provide evidence of conformity to specified requirements. Devices are listed in MIMS System. The monitoring and measuring equipment used in production and service control has been identified, adjusted, calibrated and maintained, and is capable of producing valid results. For verification several samples in Service enter and ATLAN production have been audited. Calibration of measurement equipment is performed in specific intervals (usually once a year or after 18 months) Calibration is currently done by "Kalibrierlabor Revalstr." which counts as provider. In some cases devices can be calibrated with other external partners (e.g. Testo) All measuring devices are listed and controlled in MIMS with ID-number, last calibration date, next calibration date, calibration evidence.</p>

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	<p>Responsible persons in Service Center Moisliger Allee and production get once a month an email with status of devices for notification of devices that must be calibrated.</p> <p>Furthermore, each employee of service center is responsible to check calibration status of used devices which is labeled on each device.</p> <p>Calibration certificates are stored and maintained in MIMS</p> <p>Devices are marked with an ID number and the date of the next calibration.</p> <p>Audited Examples :</p> <p>///Moisliger Allee – "Service center"///</p> <p>Secu Life PS 300 Patienten Simulator MIMS 302658 (Prüfplatz 107)</p> <p>Tempstecker 37.0 Grad Inventarnummer 302658</p> <p>PSC14 - Monitoring and measuring devices validity of previous measurements in case of non- confirming measurement devices (GM)</p> <p>The organization assesses (and records) the validity of previous measurements when equipment is found not to conform to specified requirements, and takes appropriate action on the equipment and any product affected.</p> <p>The control of the monitoring and measuring devices is adequate to ensure valid results.</p> <p>Every device which is processed in "Service Center Moisliger Allee" will be listed in SAP system with incoming date. In SAP the device will be linked to a dedicated work place with ID. Every workspace has a list of measurement equipment used unique at this place.</p> <p>In production all used test equipment will be documented in every test protocol in SAP. It will be possible to trace back every used device with related time-period and related concrete tests and test results. The status of measurement-device at time of usage can be traced back in MIMS.</p> <p>Monitoring and measuring devices are protected from damage or deterioration e.g. via limited access to the "Service Center building Moisliger Allee" and production and the floor where the devices are in usage. Every employee is taught in handling of the measurement equipment.</p> <p>No such event occurred so far.</p> <p>Samples for audited Measurement equipment with related status which have been checked at workplaces and in MIMS find under PSC 13.</p> <p>PSC15 - Validation of software used in production (GM)</p> <p>In production are parts of SAP in usage. Whole SAP tool with all used modules are validated from SW validation officers (see also docu Pavlov).</p> <p>Main used SAP Modul in production is: PLESS validation protocol have been audited</p> <p>Furthermore some teststations with SW are in use. Here the whole test station will be validated.</p> <p>One sample have been audited.</p> <p>PSC16 - Product file (HD)</p> <p>///Service Center - Moisliger Allee/// (HD)</p> <p>Technical documentation for medical device was reviewed during this audit, including risk management process, labelling, specification, Standard List, Biocompatibility Testing, etc. During design and development the design change review takes place. Please see also corresponding tasks of Design and Development chapter.</p> <p>PSC 17 - Production record; evidence of compliance of released devices</p> <p>///Service Center - Moisliger Allee/// (HD)</p> <p>The cleaning of the devices in that are received in the workshop is done by Dräger Interservice GmbH. the employees of the Service Center (sales) receive the devices and assigns them an identifier based on the Serial and Material number as well as the customer documents that are sent together with the device.</p> <p>The Service order will be set in SAP, the description of the service, for the Interservice employees and the service technicians to be able to start the failure diagnosis.</p> <p>The traceability of the whole process is ensured via SAP system. The service devices are registered and each service step is documented in SAP based on the service need e.g. code 1150 received in der service center, 1690 service start in repair center, 1700 end of service, ready to send 4000 etc. The device status in repair center is traceable at any time also service and spare parts provided are visible to the client via SAP documentation.</p> <p>The Service Connect tool (www.serviceconnect.dreager.com) will be used for the compilation of the whole service strategies of the devices, including diagrams and parts list. Maintenance documents which are used for factory services can be found on the Share Point. The service process is documented and released via SAP.</p> <p>Brazil and US requirements are full filled, the example above.</p> <p>PSC 18 - Traceability applied to life-supporting or life-sustaining medical devices</p> <p>Logistic center C45 and S4 inbound, outbound, storage, packaging (HD)</p> <p>The process is defined each working step is documented in SAP system. All materials delivered are registered in the system with incoming good receipt. The status of the goods such as quality inspection, blocked, P01 pellets stock, P03 block stock can be checked via SAP. The back traceability for delivered orders was verified during the audit see the records.</p> <p>Additional country-specific requirements:</p> <p>CANADA / US</p> <p>NA, no implantable devices in scope</p> <p>PSC 19 - Identification of product status</p> <p>Logistic center C45 and S4 inbound, outbound, storage, packaging (HD)</p>

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	<p>All products in outbound logistic center are clearly identified with labeling with the following minimum information: Part Number, Revision, Lot or serial number, expiration date where applicable and acceptance status. Particular examples assessed. Order No 1200353210 pos 10 Atlan 300 XL, delivery to Mexico Delivery documents includes unpacking instructions.</p> <p>The evidence for incoming inspection could be reviewed during the audit. The requirements document in the inspections test plan (In SAP), inspection record for the sampled part was available. The QS inspector can mark the status of incoming goods in SAP as e.g.: F1 release without defect, F4 release with rework, R – rejection, KI– needs clarification. AB 4900062419 / WE 6009269331 and AB 4900059225/ Name 60009238477 (blocked material) – The sample size for QS inspection is defined in SAP, Incoming inspection plan is saved by each material in SAP.</p> <p>PSC 20 - Customer property ///Service Center - Moislinger Alee/// (HD)</p> <p>Customer Property is identified as such with red label when received. The reception of devices from customer is managed using the service and maintenance procedure. All service orders are entered in SAP and received SAP unique service order No.</p> <p>Logistic center C45 and S4 inbound, outbound, storage, packaging (HD)</p> <p>No examples of customer property were observed in the warehouse and logistic center during the audit.</p> <p>PSC 21: Test plans and escalation schemes for in process controls, final inspection and final release are defined.</p> <p>PSC 22 - Identification, control, and disposition of nonconforming products ///Service Center - Moislinger Alee/// (HD) The identification, control, and disposition of nonconforming products in the service center is adequate. In case the device cannot be repaired it is marked in SAP with code 1750 end of service / scrap +new.</p> <p>PSC 23 - no rework</p> <p>PSC 24 - Preserving the conformity of product during internal processing, storage, Logistic center C45 and S4 inbound, outbound, storage, packaging (HD) The preservation limited with temperature and humidity levels defined for some areas of the warehouse.</p> <p>All products are initially packed at the end of production lines and transported to the Outbound logistic center where they are labeled with delivery documents/ Unpacking instructions and any additional required information. The packaging specification is deposited in material master data in SAP.</p> <p>PSC 25 - Review of customer requirements, distribution records //Service Center - Moislinger Alee/// (HD) See Task PSC-1+17</p> <p>A process to ensure a traceability is established. 0800-GWI-000104[0], Product Block Procedure (from 30-March-2018) was reviewed. Traceability of two distribution records in ERP System were reviewed. Distribution record: Ref. Service Order No 308574490. Distribution record: Ref. Order No 2221460420 LS 0175998557. Distribution record: Ref. Order No 213121773 LS 0175999693. Traceability to end customer for both distribution records was given.</p> <p>Additional country-specific requirements: BRA, USA, CAN, EU (Distribution records including name and address of consignee, quantity of products, date of dispatch and numerical control used for traceability): Manufacturer use an ERP System for distribution records, all required information are available.</p> <p>PSC 26 - installation activities ///Service Center - Moislinger Alee/// (HD) Not applicable for service center. Logistic (HD) Not applicable for logistic center the installation take place onsite by customer.</p> <p>PSC 27 - Servicing activities ///Service Center - Moislinger Alee/// (HD) See Task PSC-1+17</p> <p>Servicing activities are conducted and documented in accordance with defined and implemented instructions and procedures. Service records are used as a source of quality data in the Measurement, Analysis and Improvement process.</p> <p>(Brazil, US)</p>

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	<p>Records of servicing activities are kept with the following information: the product serviced; the control number of product serviced; the date of completion of service; identification of the service provider; description of service performed; and results of inspections and tests performed.</p> <p>Trends of service activities are evaluated during regular meetings, which allows to identify trends.</p> <p>(US)</p> <p>Service reports are evaluated to determine if the event should be reported</p> <p>PSC 28 - Risk controls applied to transport, installation, and servicing Logistic center C45 and S4 inbound, outbound, storage, packaging (HD) There are not installation and servicing activities in logistic center. For risk controls applied to transport are defined for the product during design & development process and are part of the technical documentation. The Dräger Interservice GmbH is a logistic supplier and has no access to the Risk Management Files of products.</p> <p>PSC 29 - Top management commitment to the production and service process Based on the assessment of the production and service control process, the management provides the necessary commitment to the production and service control process.</p>
Reviewed documents and records (identification and revision)	<p>PSC-1-29 DDEM SC6330 Instandhaltung und Reinigung (including Pestcontrol) Rev00.00 DCS SC 5110 Wareneinnahme und Wareneingangs pruefung Rev.01.00 DEMF-SC5120 Incoming inspection planning Rev. 02.00 SC 8901 Wareneingang SC 8907 QS Prüfung DEALL PQ 8830 Hygieneplan de. Rev 00 Presentation Dräger Service Center September 2023 Labs Group Vapore Workspace 4248 / 10 14 days SAP Workspace team ventilation 4248 / 080 14 days. Planning process retrieved/demonstrate from SAP. GCS Net Sale Top 10 products. Logistic Center Presentation Logistic center inbound. Presentation Logistic center outbound</p> <p>Prüfanweisung für Service card IPL L Samos revision 18 Prüfkarte 308450914 Material No NK06000 / Equipment no 1015880062</p> <p>DDEM SC6330 Instandhaltung und Reinigung (including Pestcontrol) Rev00.00 DCS SC 5110 Wareneinnahme und Wareneingangs pruefung Rev.01.00 DEMF-SC5120 Incoming inspection planning Rev. 02.00 SC 8901 Wareneingang SC 8907 QS Prüfung DEALL PQ 8830 Hygieneplan de. Rev 00 AB 4900062419 WE 6009269331 AB 4900059225 FA 62732117 LS 175995547 LS6009269040 AB 1200353210 DSC SC 6700-013-de-00.01 Handhabung elektrostatisch gefährdeter Bauteile DDEM SC6330 Instandhaltung und Reinigung (including Pestcontrol) Rev00.00 DEALL PQ 8830 Hygieneplan de. Rev 00 Service Order 308450914 Service Order 308579966 Material No NK06000 / Equipment no 1015880062Material No NK06000 / Equipment no 1015880062</p> <p>Prüfanweisung für Service card IPL L Samos Revision 18 Service Order 308450914 Service Order 308579966 Material No NK06000 / Equipment no 1015880062Material No NK06000 / Equipment no 1015880062 PO- a3 9109935 -de 2009- 002 Prüfprotokoll D-Vapor Service Card IPM-L SAMOS revision 3 signed 20Sep2023 Narkosemittel Charge Nummer 23E10 A32 Ablaufdatum 2026-02</p> <p>DEMF-GM2150-013-en-03.00 DEMF GM2150 : Traceability of products and components FA 62732117 FA. 6273647 LS 175995547 WE 6009269040 AB 1200353210 AB 4900062419 / WE 6009269331 AB 4900059225/ Name 6009238477</p>

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Product Service

Subsystem	Production and Service Controls - #10578 (Service Center)
	<p>PQ 8830 Abläufe zur Behandlung von Reparaturaufträge in Rapair center. Service Order 308450914 Service Order 308579966 PO- a3 9109935 -de 2009- 002 Red label Service No 000308562202 masimo Set</p> <p>Prüfanweisung für Service card IPL L Samos revision 18 www.serviceconnect.dreager.com PQ 8830 Abläufe zur Behandlung von Reparaturaufträge in Rapair center. SeService Order 308450914 Service Order 308579966 PO- a3 9109935 -de 2009- 002</p> <p>Packaging specification revision 08 b 87114896 NK 6000</p> <p>PQ 8830 Abläufe zur Behandlung von Reparaturaufträge in Rapair center. DMS OF5220-en-091-00 Material returns Distribution record: Ref. Service Order No 308574490. Distribution record: Ref. Order No 2221460420 LS 0175998557. Distribution record: Ref. Order No 213121773 LS 0175999693.</p> <p>Prüfanweisung für Service card IPL L Samos revision 18 www.serviceconnect.dreager.com PQ 8830 Abläufe zur Behandlung von Reparaturaufträge in Rapair center. Service Order 308450914 Service Order 308579966 PO- a3 9109935 -de 2009- 002 Labs Group Vapore Workspace 4248 / 10 14 days SAP Workspace team ventilation 4248 / 080 14 days. Planning process retrieved/demonstrate from SAP Material No NK06000 / Equipment no 1015880062Material No NK06000 / Equipment no 1015880062</p> <p>DWAG IN4207-de-02 Versand, Transport und Verpackung DWAGOF5213 revision 1 WI Product packaging Packaging specification revision 08 b 87114896 NK 6000</p>
Names and titles of persons interviewed	<p>Ralf Küster (Indsutrial Engineer, Service center) Martin Lieber (Medical plant Servcie center Moislinger Allee) Herr Hagedorn provides rest of participant names and roles</p> <p>***** Anlauffabrik / Startup Factory (MSz) Andreas Plöger (Kostenstellenleiter Anlauffabrik/startup Factory) Daniel Sell (Projektmanager NPI) Ulf Hagedorn (scribe) (Head of Integrated Management Systems Audit Management) Tritscher (Systems Engineer) Reimann (Project Manager) Yvonne David (Software Validation Officer + Process Owner IT4120) Michael Blanke (Software Validation Officer)</p>
Products, components, or projects reviewed	See above
Statement concerning conformity based on objective evidence reviewed for this subsystem	<input checked="" type="checkbox"/> Actions are needed for this process to conform to requirements. See audit finding list.

2.5.13 Production and Service Controls - #90464 (Revalstraße / BabyLeo)

Subsystem	Production and Service Controls - #90464 (Revalstraße / BabyLeo)
Audit trail records of	George Pavlov
Area(s) visited (location, e.g., site visited)	Location #90464 (Revalstraße) For more details related to audit location and time refer to chapter 2.2 of this report.
Audit criteria according to audit plan	<p>"Production and Service Controls: Planning of Production and Service Process (MDSAP Chapter 6, Task 1, Site: 10578); (DIN)(EN) ISO 13485 - 7.1, 7.2.1, 7.5.1 + (DIN)(EN) ISO 9001 - 8.1, 8.2.2, 8.5.1 + MDSAP - Australia - TG(MD)R Sch 1 P1 2, Sch3 P1 C11.4(4), Sch3 P1 C11.4(5)(d)&(e) + MDSAP - Brazil - RDC ANVISA 16/2013: 2.2.1, 2.4, 4.1.2, 4.1.7, 5.1 + MDSAP - Japan - MO169: 26, 27, 40 + MDSAP - USA - 21 CFR 801, 820.30(b), 820.20(a), 820.30(h), 820.70(a), 830 + MDR - Article 10.9 ¶3 (g) + MDD - Annex II (3.2), Annex V (3.2)"</p> <p>Production and Service Controls: Selection of Production and Service Process(es) (MDSAP Chapter 6, Task 2, Site: 10578)</p> <p>"Production and Service Controls: Infrastructure (MDSAP Chapter 6, Task 5, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 6.3, 7.5.1 + (DIN)(EN) ISO 9001 - 7.1.3, 7.5.1, 8.5.1 + MDSAP - Brazil - RDC ANVISA 16/2013: 5.1.2, 5.1.5 + MDSAP - Canada - CMDR 14 + MDSAP - Japan - MO169: 6, 24, 40 + MDSAP - USA - 21 CFR 820.70(g), 820.70(f) + MDR - Annex IX2.2 ¶1"</p> <p>"Production and Service Controls: Work Environment (MDSAP Chapter 6, Task 6, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 6.4 + (DIN)(EN) ISO 9001 - 7.1.4, 7.5.1 + MDSAP - Australia - TG(MD)R Sch1 P2 7.2, 8 + MDSAP - Brazil - RDC ANVISA 16/2013: 5.1.3 + MDSAP - Japan - MO169: 6, 25-1, 25-2; [Old: 6, 25] + MDSAP - USA - 21 CFR 820.70(c), 820.70(d), 820.70(e) + MDR - Annex IX2.2 ¶1; Annex I (11) + MDD - Annex II (3.2), Annex V (3.2)"</p> <p>"Production and Service Controls: Identification of Processes Subject to Validation (MDSAP Chapter 6, Task 7, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 4.1.6, 7.5.6 + (DIN)(EN) ISO 9001 - 4.4, 7.5.1, 8.4, 8.5.1 + MDSAP - Australia - TG(MD)R Sch1 P2 8.2, 8.3; Sch3 P1 1.4(5)(d) + MDSAP - Brazil - RDC ANVISA16/2013: 5.5.2, 5.5.3 + MDSAP - Japan - MO169: 6, 5-6, 45; [Old: 6, 45] + MDSAP - USA - 21 CFR 820.75(a) + MDR - Annex IX 2.2 ¶2 (d); Annex XI 6.2 ¶2, 12"</p> <p>"Production and Service Controls: Monitoring and Measurement of Product Conformity (MDSAP Chapter 6, Task 10, Site: 10578); (DIN)(EN) ISO 13485 - 7.1, 7.5.1, 8.1, 8.2.6 + (DIN)(EN) ISO 9001 - 8.1, 8.5.1, 8.6, 9.1.1 + MDSAP - Australia - TG(MD)R Sch1 P1 2, Sch3 P1 1.4(5)(b)&(e) + MDSAP - Brazil - RDC ANVISA 16/2013: 2.4, 5.1.1, 9.1 + MDSAP - Japan - MO169: 26, 40, 54, 58, 59 + MDSAP - USA - 21 CFR 820.70(a), 820.250(a) + MDR - Article 10.9 ¶3 (m); Annex IX 2.2 ¶2 (b2, e); + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>"Production and Service Controls: Control, Operation, and Monitoring of the Production and Service Process; Risk Controls (MDSAP Chapter 6, Task 11, Site: 10578); (DIN)(EN) ISO 13485 - 7.1, 7.5.1, 8.1, 8.2.5 + (DIN)(EN) ISO 9001 - 8.1, 8.5.1, 9.1.1 + MDSAP - Australia - TG(MD)R Sch1 P1 2, Sch3 P1 1.4(5)(b)&(e) + MDSAP - Brazil - RDC ANVISA 16/2013: 2.4, 5.1.1, 5.1.6, 8.2, 9.1 + MDSAP - Japan - MO169: 26, 40, 54, 57 + MDSAP - USA - 21 CFR 820.70(a), 820.75(b), 820.250 + MDR - Article 10.9 ¶3 (m); Annex IX 2.2 ¶2 (b2, e); "</p> <p>"Production and Service Controls: Competence of Personnel (MDSAP Chapter 6, Task 12, Site: 10578); (DIN)(EN) ISO 13485 - 6.2 + (DIN)(EN) ISO 9001 - 7.2, 7.3 + MDSAP - Australia - RDC ANVISA 16/2013: 2.3.2 + MDSAP - Japan - MO169: 22 + MDSAP - USA - 21 CFR 820.25, 820.70(d), 820.75(b) + MDR - Annex IX2.2 ¶1"</p> <p>"Production and Service Controls: Control of Monitoring and Measuring Device (MDSAP Chapter 6, Task 13, Site: 10578); (DIN)(EN) ISO 13485 - 7.5.1, 7.6 + (DIN)(EN) ISO 9001 - 7.1.5, 8.5.1 + MDSAP - Australia - TG(MD)R Sch3 P1 1.4(5)(e) + MDSAP - Brazil - RDC ANVISA 16/2013: 5.1.5, 5.4 + MDSAP - Japan - MO169: 40, 53 + MDSAP - USA - 21 CFR 820.70(g), 820.72 + MDR - Annex IX 2.2 ¶2 (e); Annex XI 6.2 ¶2, 12 ¶1 + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>"Production and Service Controls: Impact Analysis of Monitoring and Measuring Device Found Out of Specifications (MDSAP Chapter 6, Task 14, Site: 10578); (DIN)(EN) ISO 13485 - 7.6 + (DIN)(EN) ISO 9001 - 7.1.5 + MDSAP - Australia - TG(MD)R Sch3 P1 1.4(5)(e) + MDSAP - Brazil - RDC ANVISA 16/2013: 5.4 + MDSAP - Japan - MO169: 53 + MDSAP - USA - 21 CFR 820.72(a) + MDR - Annex IX 2.2 ¶2 (e); Annex XI 6.2 ¶2, 12 ¶1 + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>"Production and Service Controls: Device Master File (MDSAP Chapter 6, Task 16, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 4.2.3, 7.1, 7.5.8, 7.5.9.1 + (DIN)(EN) ISO 9001 - 7.5.1, 8.1, 8.5.2 + MDSAP - Australia - TG(MD)R, Sch1 EP13, Sch3 P1 1.4(5)(c),(d),(e) + 1.9 + MDSAP - Brazil - RDC ANVISA 16/2013: 1.2.26, 2.4, 4.2, 5.2, 6.4 + MDSAP - Canada - CMDR 9(2), 21-23, 52-56, 66-68 + MDSAP - Japan - MO169: 6, 7-2, 26, 47, 48; [Old: 6, 26, 47, 48] + MDSAP - USA - 21 CFR 820.65, 820.120(e), 820.181 + MDR - Article 10.4 ¶1, 10.5, 10.9 ¶3 (b), 10.11, 10.15; Annex IX 2.2 ¶2 (c6); Annex XI 6.1 ② & 12 ¶1 + MDD - Annex II (3.2), Annex VI (3.1)"</p> <p>"Production and Service Controls: Production Record; Evidence of Compliance of Released Devices (MDSAP Chapter 6, Task 17, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 7.5.1, 7.5.8, 7.5.9.1, 8.2.6 + (DIN)(EN) ISO 9001 - 7.5.1, 8.5.1, 8.5.2, 8.6 + MDSAP - Brazil - RDC ANVISA 16/2013: 3.2, 5.2, 6.4 + MDSAP - Japan - MO169: 6, 40, 47, 48, 58, 59 + MDSAP - USA - 21 CFR 820.120, 820.184 + MDR - Article 10.7, 10.9 ¶3 (h); Annex IX 2.2 ¶2 (c7); Annex XI 12 ¶1 + MDD - Annex II (3.2), Annex V (3.2)"</p> <p>"Production and Service Controls: Acceptance Activities (MDSAP Chapter 6, Task 21, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 7.4.3, 7.5.8, 8.2.6 + (DIN)(EN) ISO 9001 - 7.5.1, 8.4.2, 8.4.3, 8.5.2, 8.6 + MDSAP - Australia - TG(MD)R Sch1 P1 2, Sch3 P1 C11.4(5)(d) + MDSAP - Brazil - RDC ANVISA 16/2013: 5.3.1, 5.3.2, 5.3.3, 5.3.4, 9.2 + MDSAP - Japan - MO169: 6, 39, 47, 58, 59 + MDSAP - USA - 21 CFR 820.80, 820.250(b) + MDR - Article 10.9 ¶3 (m), Annex IX 2.2 ¶2 (b2, e); Annex XI 6.2 ¶2, 12 ¶1 + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>"Production and Service Controls: Identification, Control, and Disposition of Nonconforming Products (MDSAP Chapter 6, Task 22, Site: 10578); (DIN)(EN) ISO 13485 - 7.5.8, 8.3 + (DIN)(EN) ISO 9001 - 8.5.2, 8.7 + MDSAP - Australia - TG(MD)R Sch1 P1 2, Sch3 P1 C11.4(5)(b) + MDSAP - Brazil - RDC ANVISA 16/2013: 6.5.1, 6.5.2 + MDSAP - Japan - MO169: 47, 60-1, 60-2, 60-3, 60-4; [Old: 47, 50, 60] + MDSAP - USA - 21 CFR 820.60, 820.90(a), 820.86, 820.100(a) + MDR - Article 10.9 ¶3 (k), 10.12; Annex IX 2.2 ¶2 (b2); Annex XI 6.2 ¶2, 12 ¶1 + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p>
Brief description of processes or activities evaluated to demonstrate what was audited related to the listed key QMS documents and records reviewed below considering inputs, outputs, and measures	<p>PSC1 - Planning of production and service process Drager has created and implemented the process and procedure related to the production process.</p> <p>//Production Control device Baby Leo TN500 //GP] Production is performed a B23 The production is made order based. Production process is organized as series of workstations, the product is pushed manually from one step to another. The production records section is completed electronically after Each work station – based on so called production router records. At each section of production step is limited to 20 minutes. The Organisation structures, the responsibilities and authorities related to Production were demonstrated - the product belongs to the unit Customer Order execution Waermeterapy</p> <p>Short product overview was provided on request during the audit Babyleo TN500 is an incubator and a radiant warmer for use with premature babies and neonates. The IncuWarmer Babyleo TN500 provides controlled ambient conditions for premature babies and neonates. The following parameters are regulated, according to the intended use: – Temperature – Humidity – Oxygen (option)</p> <p>Total production quantity is 1600 production a year. The materials supplied to production – based on KANBAN principle (two boxes for the particular par are positioned at each location, the empty box is replenished automatically from the warehouse M5. Special environment – only maintained in the Functional Test area – the room is Climate controlled – temperature control , humidity – no control , particles – no requirement.</p> <p>United States (FDA): The organisation applies UDI identifier and Serial number / Batch number to all devices. The documented UDI DI was demonstrated:</p>

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	<p>MDR 106091 Babyleo TN500 Document of STED Ver 6 202-11-09</p> <p>Part No 2M60000 / BabyLeo TN 500 Basic UDI DI 040486751306011VK19Z0008, Main GTIN (UDI DI) 04048675436607 GTIN is issued by GS1 UDI data Set is documented in Attachment</p> <p>PSC-2 – Selection of production and service process(es) Line 1 – Babyleo was sampled in line with overall sampling plan for Drager as new device not audited in respect of production. The selection was defined in line with Sampling plan Final production and functional test were selected as process with direct impact to safety and performance.</p> <p>PSC-5. – Infrastructure The process for control of the infrastructure is defined in DEMF SC6330 Instandhaltung und Reinigung. The decision on the specific requirement for maintenance of the equipment is performed, when the new process or equipment is introduced according to Qualification of Production. The result of initial evaluation of production equipment shall be documented as DEMF SC6330_A06 Betriebsmittel/- Anlagenbewertung</p> <p>Based on the areas observed during the audit in production (Building B23), the production areas are well organised and maintained.</p> <p>The verification in respect of Water supply preparation system was performed – the statement of the manufacturer, no maintenance was planned as the quality of water is measured based on the conductivity meter – conductivity of 2 to 30 mkS/cm was demonstrated, with max permissible level 20 mikS/cm. The manufacturer instruction was demonstrated – no requirements for periodic maintenance were defined. Accepted based on observed water conductivity well within defined framework.</p> <p>ESD measures are applicable across all production area. Those include the conductive flooring, equipotential connections to all equipment, presents of ESD mats on the work benches (observed during the audit at Babyleo production), use of ESD furniture and clothing. The presence of control station for ESD check uniform foot ware was verified by the auditor.</p> <p>The periodic inspection of ESD measures is performed twice a year – the last inspection report demonstrated, the reports confirms in-depth testing of the conductivity in production area – including the floor surfaces (conductivity in the region of 22 – 25 MOhm was achieved) and testing of the furniture and work benches.</p> <p>Brazil adequate means for people flow. Was assured in production areas – verified by visual inspection during the audit at Building B23</p> <p>PSC-6. – Work environment In the audited production area Baby Leo, building 23, no special environmental requirements applied, with exception of Functional test Lab.</p> <p>In the Functional test area, the control of temperature is implemented. Within the span of 20...25C. The temperature is logged during the active test performance, the calibration of the temperature measurement system was verified during the audit. Note: the organisation has adopted the cleanroom process, this was verified as part of the audit in another production area</p> <p>Brazil Biosafety standards were not applicable in the sample date of production – no use of chemical was observed. The water used in functional testing is soft water (de-ionized) – not relevant for biosafety.</p> <p>PSC 7 - Identification of processes subject to validation The Identification of the process subject for validation is performed as a part of Transfer to production. The organisation has not identified any production processes subject to validation with Babyleo TN500. This was challenges by the auditor during the observation on the production floor – nevertheless, no process subject to validation were observed in Production area for Baby Leo. The processes is 100%, final assembly does not include gluing, welding or soldering.</p> <p>Brazil NA- the processes subject to validation were identified for Babyleo TN500 US NA – in the sampled and audited production are no sterilization, aseptic processing, injection molding, and welding were observed</p> <p>PSC 10 - Monitoring and measurement of product conformity Product conformity is verified during the performance of in-production and final tests, with test procedures documented and available electronically as part of eDMR and were demonstrated during the audit as so called Production steps</p>

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	<p>(Vorgang), specifically the test steps shall be documented as Prüfanweisung according to DEMF SC6500 Documentation von Produktionsprozessen, the records documented as a part of electronic DHR. ///Baby Leo Production Building B23 Line 1// [GP] In the sampled are of production for baby Leo devices, following steps were observed during the audit: Electrical safety Test</p> <p>Electrical safety test – finished Basis-device with High Voltage Tester: Id 302303(HiPot) and 3032338 (Leakage Current) Safety test Operating instruction W01-0012</p> <p>Final Function test (basis-device) Functional test / incl temperature test for TN500 S/N 2M6001-19-ASSK-0088 Temperature Test was observed in production for Device Order 65577324 Average temperature / Maximum temperature test was observed and record verified according to Final performance AV0-3220 Final / Performance test Link to measurement equipment observed for humidity meters at functional test area 1) ID506091 /4214 2) ID505128 /4214 Linkage to the temperature measurement system observed ID 505278 / 4214</p> <p>Water preparation station for Humidity generator in functional testing: the de-ionising filter with conductivity meter Water Conductivity meter – identified ID 2800, water preparation unit installed 23.01.2016</p> <p>Operator demonstrated the Functional /Temperature testing – Marius Wydra</p> <p>The verification of skin sensor (externally connected part) was not observed in final Function production – its was explained this test is performed at in-process production station. This was verified for one finished device based of DHR: Work Plan material Base device TN 500 Planer 5006010 Rev 5 Vorgang 3190 Arbeitsplatz 4214 /012 Test of the skin temperature 39.5</p> <p>PSC 11 - PControl, operation, and monitoring of the production and service process; risk controls ///Baby Leo Production Building B23 Line 1// [GP] The pre-production of the assemblies and pre-finished devices is built anonymously to the production assembly warehouse M5 – and completed on the specific production order for individual customer. 5 Assembly Work Stations observed in final production area – Software download - - Electrical safety test – Final performance test (Environment control) -> Local assembly layer (customer neutral devices) - -> customizing station – (customization station by the specific customer order) - -> Electrical safety test (repeated) -> Functional test and Language seeing for the client - Internal waiting areas - -> The final production and release is performed in two stages: - Production of basic device – customer neutral / unconfigured - Configuration of finished device, including installation of particular SW / Partial retest and release packaging and dispatch. The packaging B3B – packaging in the separate Building.</p> <p>After the construction has been finished, the devices go to the hall B3, to be packed and sent to the customer. There is a working plan, which is distributed according working places, (paperless production) and controlled through SAP, which indicates which production steps have been completed and allow the device to continue the assembly. The whole order paper and preparation documents are linked to the order. In the case additional information is needed of has to be provided, the supporting documents are linked to the working place.</p> <p>The processes used in production are appropriately controlled, monitored, operated within specified limits and documented in the product realization records. The electronic assembly and test instruction were observed. He auditor has observed assembly operation – assessment was performed that operation are performed in line with defined Work Instructions and defined parameters, following operation selected and observed on production floor 1. Trolley assembly Installation of Hubsale LINAK Part Nr 2M60521-08 Production Order records performed in PLESS (Paper less Order system) Installation of Separation Power supply ZP/N 8421200-09 S/N ASSE-507</p> <p>Assembly of the trolley – installation of Radiant Heater – checked if torque screwdrivers correctly applied during the production operations; Drawing 2M60600-09 Radian of Radiant Heater assembly Verified if the Torques screwdrivers correctly identified and used - verified actual Torque screwdrivers to the drawing 1) Screwdriver 1.8 NM – screwdriver ID416048/4217 2) Screwdriver 8NM – ID 415989 The Torque settings were verified against the drawing – found in line with drawing requirements W01-006Radiant heater assembly work station 4 for Production Order 6557743 S/N 2 M600-1-19-ASSK-0106</p> <p>Australia The production observed in line with required parameters and documented instruction. No devices for Australia were observed, it was explained the devices are manufactured as country-neutral for subsequent labelling and packaging</p> <p>PSC 12 - Competence of personnel</p>

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	<p>Competency / Training records verified in respect to the production operate in the Final Function ? temperature test Babylog TN 500 – train records were demonstrated in relation to the operation performed during the audit. Training for Final release of production records Arbeits Vorganag 1590 was verified in relation of Operator Dirk Schnoor – who was observed as released DHR at last step of basis Device – demonstrated during the audit</p> <p>PSC 13 - Control of monitoring and measuring device It was observed that measurement equipment in production area are identified with individual ID numbers, also the measurement equipment which used as part of production rigs / stations. The measurement equipment critical for safety and performance was sampled and verified during the audit: Calibration certificate. US 416581 Torque controlled wrench - Calibration certificate by Test valid 28.10.2020 Electrical screwdriver Additionally, calibration certificates were verified for Temperature measurement station / Functional test Temperature Measurement Station ID 505278 / 4214. It was confirmed the calibration was performed in time and includes both multichannel station and related thermocouples.</p> <p>PSC 14 - Impact analysis of monitoring and measuring device found out of specifications Impact is investigation in relation of the instrument, which failed calibration - investigation demonstrated: the decision to write of the instruments, the analysis of the impact was performed in respect of the medical devices, According to justification, the torque of the wrench, which failed calibration was within the tolerated are - statement: no additional risk observed, the investigation performed by the device responsible manager.</p> <p>PSC 16 - Device master file He DMR is generated according to the DEALL PQ3130_A02 - Rev 04.02 This document defines the summary of the documentation, which must be prepared as part of the DMR. ///Example – DMR Baby Leo TN500/// [GP] The set of documents straws provided during the audit as evidence of the documented DMR. Element of DMR were produced 9054863_09 IfU Babyleo TN500 SW 1.0n EN 2021-06-22 2M60003_17 Produktions- und Test Specification BABYLEO TN500 2023-01-16 2M60002_11 Assembly_TN500 2M60002 – 11 Assembly Drawing top level 2022-12-09 2M60002_11 Part- Specification for Assembly TN500 2022-12-09 2M60000_29 AP_HA_HP Druckliste Arbeitsplan – 2M60000 the list for Work Instruction 22.09.2023 2M60000_29 Part- Specification for Babyleo TN500 2023-02-22 2M60000_28 Information für Rückverfolg Rev 28</p> <p>Australia / Brazil / Canada DEMF SC_A6200_A02-de-01 Erläuterung und darstellung – The review- and approval of DHR ASRM 0019 07.11.2022 The release of the Label is documented and approved in DHR Verification of the Label – according to the to DEMF SC6400_A01-de-00 The labelling is printed directly in the production and verified as part of the final release according to according to the to DEMF SC6400_A01-de-00</p> <p>/ US Each device maintains the Serial Number which is used for traceability</p> <p>PSC 17 - Production record; evidence of compliance of released devices The DHR is formed at the production of top-level sub-assemblies and is defined as sub-DHR , the linked to the top-level DHR for Basis device, and subsequently the DHR for the finished configured device via serial numbers of subassemblies and finished device.</p> <p>DHR was sampled from the distribution list and demonstrated during the audit for the device TN500 ASRL 0056 The auditor has observed the final approval and review stage from production of Babyleo TN500 Basis device – it was explained that DHR is regarded as approved if all sub-DHRs are completed without errors, and accepted this is an automatic step in SAP. The review is confirmed by the electronic signature of the operator</p> <p>Brazil Device history record of the product includes date of manufacture; components used; quantity manufactured (usually – 1 pcs as DHR is documented for one device); results of inspections and tests; parameters of special processes; quantity released for distribution; labeling; identification of the serial number or batch of production; and final release of the product [The approval, including date, name, and electronic signature of the person responsible, must be documented is documented.</p> <p>US The process is defined in DWAG PQ2140-en-04.00. Labels are printed and issued to production for each individual device, verification is performed by the Operator in production line. UDI is established and maintained – verified during the audit:</p> <p>Part No 2M60000 / BabyLeo TN 500 Basic UDI DI 040486751306011VK19Z0008, Main GTIN (UDI DI) 04048675436607</p>

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	<p>GTIN is issued by GS1 UDI data Set is documented in Attachment</p> <p>PSC 21 - Acceptance activates The process is defined in DCS SC5120 Incoming Inspection Planning The process starts with the review of critical parts, for each critical part, the Inspection Plan shall be documented and Inspection characteristics shall be defined. For initial receiving DCS SC5130 First Article Inspection (FAI) shall be performed.</p> <p>Records of successful inspection demonstrated as following Example observed for the Part 368451 The test protocol incoming inspection Part 8421200 N 3 parts were checked from overall 192 incoming batch.</p> <p>Additional country-specific requirements: United States (FDA): Brazil (ANVISA): SC 5121 Incoming Inspection Rev 01. – defines the Dynamic rules for the sampling The AQL sampling according to DIN 2859-1 According to DCS SC5120 Incoming Inspection Planning The rules for inspection severity according to DIN ISO 2859-1 allow a change of the sampling procedure regarding sample size from normal, increased and reduced, depending on the inspection results for lots supplied before.</p> <p>PSC 22 - Identification, control, and disposition of nonconforming products SC6110 – Non-confirming material The NC devices are identified with dedicated red label, the FQ (number (NC- Message) is raised in SAP The list of NC devices was demonstrated – the 590 NC records related to parts The NC parts were observed in production – respectively identified, Isolates, traceable by so called FQ Numbers Example of NC materials were sampled in production quarantine area and assessed during the audit: FQ 810000399249 Abdeckung Heizstrahlerarm, Gewinde abgebrochen – registered 05.06.2023 Decision – 06.06.2023 – scrap – no additional investigation</p> <p>FQ 810000416716 13.09.2023The heating element - - in process - the parts were isolated</p> <p>FQ 810000359190 02.11.2022 temperature outside of tolerance – the failure in basis device TN500 ASRL 0056 - Norwandmotage - - Rework – - errored part ASRJ 0460 - - The evidence the part was reworked and retested was found in DHR for the S/N TN500 ASRL 0056, Completed 03/11/2022</p>
Reviewed documents and records (identification and revision)	<p>Control of DMR and DHR DEMF SC6500 Documentation von Produktionsprozessen DEMF SC6500 - de - 02, Rev. 2 DWAG PQ2140 International Labeling Requirements for Medical Devices, Rev. 04.00 DCS SC6110 Behandlung von Abweichung in der Produktion Ver 00</p> <p>Production DWAG IN4300 New Product Introduction, Rev. 09.00 DEMF SC6100 Qualifizierung in der Fertigung DEMF - SC6100 - de - 00.00, Rev. 00.00 DEMF SC6200 Produktherstellung DEMF SC6200 - de - 02, Rev. 2 DEMF SC6210 Fertigungsauftrag - Fremdbearbeitung DEMF SC6210 - de - 01.00, Rev. 01.00 DEMF SC6220 Reparatur - Austausch - Teile (RAT) DEMF - SC6220 - de - 00, Rev. 0</p> <p>Packaging / Traceability / Identification / Release DEMF GM2150 Rückverfolgbarkeit von Produkten und Komponenten, Rev. 02.00 DWAG OF5310 Maschinenlesbare Codierung, Rev. 04 DWAG PQ2110 Regulatory Approval to Market Product, Rev. 02.00</p> <p>Infrastructure / Environment / Cleanliness DEMF SC6400 Handhabung von Material und Hilfsstoffen DEMF SC6400 - de - 00, Rev. 0 DEMF SC6700 Handhabung elektrostatisch gefährdeter Bauteile (ESD) DEMF - SC6700 - de - 00.01, Rev. 00.01 DEMF SC6720 Schutz vor elektromagnetischen Einflüssen in der Produktion DEMF SC6720 - de - 00, Rev. 0</p> <p>Non-confirming product DEMF SC6111 Lenkung von fehlerhaftem Material DEMF - SC6111 - de - 00.01, Rev. 00.01 DEMF SC6110 Behandlung von Abweichungen in der Produktion DEMF - SC6110 - de - 00.00, Rev. 00.00 DEMF SC6130 Produktionsstopp und Lieferstopp DEMF - SC6130 - de - 00.00, Rev. 00.00</p> <p>DEMF SC6110 Behandlung von Abweichungen in der Produktion, Rev. 00.00 (??) DEMF SC6120 Qualitätskennzahlen in der Produktion, Rev. 00.00 ??</p> <p>Incoming inspection and acceptance DEMF SC5120 Incoming Inspection Planning DEMF - SC5120 - en - 02.00, Rev. 02.00 DEMF SC5210 Umgang mit mangelhaftem Einkaufsmaterial DEMF SC5210 - de - 01.01, Rev. 01.01 DEMF SC6010 Inward stock movement DEMF SC6010 - de - 01, Rev. 1 DEMF SC5130 First Article Inspection (FAI) DEMF SC5130 - de - 02.00, Rev. 02.00 MMDR 106091 Babyleo TN500 Document of STED Ver 6 2022-11-09</p>

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	<p>babyleo-tn500-ifu-9054863-en Instruction for Use Babyleo TN500 Booklet babyleo-tn500-pi-9102128-en-master Marketing brochure neonatal-and-pediatric-accessories-ca-9066934-en Production Layout Production Babyleo TN500 – as on the day of the audit</p> <p>CS Hoses Risik assesemnt V2.3 2023-07-04 Production Risk Control measure: CS_RM-566 The product shall be delivered Clean but not sterile CS-TSR-432 The Product shall not have a level of hydrocarbon greater than 550mg/spm and be free from particles acc. To ISO15001 Verification report CS_TRS_156_TR3 Test report 14-00128-PR-004 rev. 0 □ Test Result: Particle measureent, Oils Content, Ignition temperature passed.</p> <p>DEMF SC6330 Instandhaltung und Reinigung Rev 00 DCS SC6100 Qualifizierung in der Fertigung Rev 00.00 Identification of water cartridge and Instruction for the water cartridge DI2800 installed 23-01-2016 ESD test protocol Werk 3 Building B23 13.04.2023 DWAG OF4160 Betreiben von Reinraumprozessen DWAG - OF4160 - de - 00 , Rev. 0 Temperature records Functional test area Babyleo production Order 65577324 2023-09-22</p> <p>Functional test / incl temperature test for TN500 S/N 2M6001-19-ASSK-0088 AV0-3220 Final / Performance test Functional final temperature test record Device Order 65577324 performed – in production on day of the audit Work Plan material Base device TN 500 Planer 5006010 Rev 5 Vorgang 3190 Arbeitsplatz 4214 /012 TN500 Vorganag 3250 Work Instruction Functional test TN500</p> <p>W01-006Radiant heater assembly work station 4actual on the day of the audit Prodcuation Order 6557743 S/N 2 M600-1-19-ASSK-0106 – open on the day of the audit</p> <p>Training record Operator Marius Wydra Arebeitsvorgang 3250 Work Instruction Functional test TN500 – actual Training record Operator Dirk Schnoor Arbeitsvorgang 1590 Final release assembly basis device–actual</p> <p>US 416581 Calibration certificate Torque controlled wrench by Test valid 28.10.2020 DEALL PQ3130_A02 - Rev 04.02 Control of Documents and Recordss RMB 400760 /2022-10-12 Investigation Toque wrench – failed calibration Calibration CERTIFICATE id400760 Wrench Hazet by test lab, 12.10.2022 99054863_09 IfU Babyleo TN500 SW 1.0n EN 2021-06-22 2M60003_17 Produktions- und Test Spezifikation BABYLEO TN500 2023-01-16 2M60002_11_Assembly_TN500 2M60002 – 11 Assembly Drawing top level 2022-12-09 2M60002_11 Part- Specification for Assembly TN500 2022-12-09 2M60000_29_AP_HA_HP Druckliste Arbeitsplan – 2M60000 the list for Work Instruction 22.09.2023 2M60000_29 Part- Specification for Babyleo TN500 2023-02-22 2M60000_28 Information für Rückverfolg Rev 28</p> <p>DEMF SC6500 Dokumentation von Produktionsprozessen Rev00 DWAG PQ2140-en-04.00 International Labeling Requirements - for Medical Devices DHR for Babylog TN500 ASRL 0056</p> <p>DCS SC5120-en-013-02.00 Incoming Inspection Planning DCS SC6110 Behandlung von Abweichung in der Produktion Rev 00 DCS SC6111 Lenkung von fehlerhaftem MaterialRev 00.01 DCS SC6120 Qualitätskennzahlen der Produktion Rev00 DCS SC6220-Reparatur-Austausch-Teile (RAT)-013-00 DCS SC6130 Produktionsstopp und Lieferstopp Rev 00 FQ 810000399249 NC Record Abdeckung Heizstrahlerarm, Gewinde abgebrochen – registered 05.06.2023 FQ 810000416716 NC-record the heating element 13.09.2023 FQ 810000359190 temperature outside of tolerance – the failure in basis device TN500 ASRL 005602.11.2022</p>
Names and titles of persons interviewed	<p>Product focus: Line 1 – Babyleo Production area Baby Leo TN500 Factory 3 Building B production area B23</p> <p>Timo Harms Director Quality & Regulatory Affairs BU HCA Jan Paulssen Supplier Quality Manager - BU HCA Jochen Meyn Quality Manager BU Therapy Dirk Geisteier Bereichsleiter Hasan Tatli Industrial Engineer Tobias Scotti Product Quality Manager Stephan Both Quality System Manager Auditing Constantin Lüthjw Team Leiter Bereich Babyleo Nico Zeitz Quality Engineer Marius Wydra Operator Dirk Schnoor Operator Thomas Schoop Product Owner BabyLeo Luba Lange Regulatory Compliance Sebastian Maerz (Scribe) Product Quality Manager - BU Therapy</p>

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	Sussan Tapy – Anestesy Konstantin Ludky Tobias Scotty Sebastjan Maerz – Quality Therapy
Products, components, or projects reviewed	See above
Statement concerning conformity based on objective evidence reviewed for this subsystem	<input checked="" type="checkbox"/> Actions are needed for this process to conform to requirements. See audit finding list.

2.5.14 Production and Service Controls - #90464 (Revalstraße / HM Filter)

Subsystem	Production and Service Controls - #90464 (Revalstraße / HM Filter)
Audit trail records of	Melanie Gaßen
Area(s) visited (location, e.g., site visited)	Location #90464 (Revalstraße) For more details related to audit location and time refer to chapter 2.2 of this report.
Audit criteria according to audit plan	<p>MDSAP Tasks: #1-2, #5-7, #11-14, #16-17, #20-22, #25-27, #29 ISO 13485:2016, 7.5 ISO 9001 MDR PRODUCTION AND PROCESS CONTROLS Annex IX.2.2d) & e), XI.6.2</p> <p>Specific Personnel Competency and Training ISO 13485: 6.2 ISO 9001: 7.2, 7.3, 7.5.1</p> <p>MDR: Annex IX 2.1, 2.2 (a), Article 15, [MPDG §83] MDD: Annex II (3.1, 3.2), Annex V (3.1, 3.2), Annex VI (3.1)</p>
Brief description of processes or activities evaluated to demonstrate what was audited related to the listed key QMS documents and records reviewed below considering inputs, outputs, and measures	<p>*****HME / filter production line (MGa)</p> <p>PSC-1 ISO 13485:2016: 7.1, 7.2.1, 7.5.1; Process Description: The Manufacturer has implemented a product realization processes that including any necessary controls, controlled conditions, and risk management activities required for the product to meet the specified or intended uses, the statutory and regulatory requirements related to the product, and (when applicable) unique device identifier requirements. Planning of product realization is consistent with the requirements of the other processes of the quality management system and performed in consideration of the quality objectives. For the selected process, the production and service process that is planned and conducted under controlled conditions has been audited.</p> <p>Planning of product realization is consistent with the requirements of the other processes of the quality management system and performed in consideration of the quality objectives. Business Manager establish a forecast, production is relaying on demand. A safety stock is implemented to be able for distribution at any time. The logistic is responsible for the availability of raw material to be ready for production. The production order is controlled by logistic and is feed into SAP. In SAP Hejunktboard shows the realization process.</p> <p>US: The UDI will be issued under the GS1 scheme. The information will be converted into a data matrix code, which is on the product label. A procedure is in place.</p> <p>The following samples are taken based on the following criteria: Availability, as the Humidstar 25 Plus is produced at the time of the audit.</p> <p>PSC-2 ISO 13485:2016: 7.1, 7.2.1, 7.5.1 Process Description: At the time of the audit the HME Humidstar 25+ had been produced on the AFO-line. For the selected process, the production and service process are planned and conducted under controlled conditions that include the following:</p> <ul style="list-style-type: none"> - the availability of information describing product characteristics - the availability of documented procedures, requirements, work instructions, and reference materials, reference measurements, and criteria for workmanship - the use of suitable equipment - the availability and use of monitoring and measuring devices - the implementation of monitoring and measurement of process parameters and product characteristics during production - the implementation of release, delivery and post-delivery activities - the implementation of defined operations for labeling and packaging - the establishment of documented requirements for changes to methods and processes <p>Inputs to the production plan are inventory and sales order information from sales forecast information. The production of HME and filter is conducted on an automatic production line, the line requires the input of components (housing bottom and top, medium (foam) and filters (when applicable), the output is the ready packed distribution unit (devices packaged in blister with Tyvek lid, wrapped in double bags and boxed in a labeled carton box, including IFUs).</p> <p>The production-line is located in clean room, ISO class 8. A Material lock and a separate lock for operators are implemented, the material flow is defined: Double bag into material lock; outer bag disposed; inner bag into the cleanroom Incoming rawmaterial is located in the production area, outside the cleanroom. At location shelf life check is requested</p> <p>PSC -5</p>

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	<p>ISO 13485:2016: 4.2.1, 6.3, 7.5.1; Process Description: Dräger realizes that product quality can be influenced by the production work environment. Dräger directs, regulates, coordinates, and monitors activities and variables that affect the conditions such that the quality of the work environment is known. Manufacturing equipment is designed, constructed, installed, and located to facilitate proper operation, maintenance, adjustment, and cleaning. The organization has determined and documented the infrastructure requirements to achieve product conformity, including buildings, workspace, process equipment, and supporting services. Buildings, workspaces, and supporting services allow product to meet requirements. There are documented and implemented requirements for maintenance of process equipment where important for product quality, and that records of maintenance are maintained. In the Cleanroom the monitoring of temperature and humidity is ensured by continuously measuring by installed sensors. For the access of the cleanroom, material and personal locks are separated. Clear instruction for entrance are available.</p> <p>PSC -6 ISO 13485:2016: 4.2.1, 6.4; TG Process Description: Please see also task PCS 5 Hygiene instruction are outlined, protection equipment such as coat, hair/ facial hair cover and shoe covers are mandatory for entering the cleanroom. Equipment permitted in the cleanroom are mobiles, cosmetics and jewelries, persons with pacemakers are permitted to enter the cleanroom. Monitoring of cleanroom is conducted twice a week, Tuesday and Thursday . In operation the particle count is conducted. 26 sampling locations are defined; sonde is located of the height of activities. Exceptional measuring reasons are given, e.g. in case of a black out Alarm and Action level and limit exceeding are defined: according to ISO 14644-1 The maintenance of the cleanroom is outsourced to Dräger Gebäude und Service GmbH. If action limit is exceeded, required actions are defined, such as e.g. information to dedicated responsible persons, Change of Air input sacks:</p> <p>PSC-7: ISO 13485:2016: 4.2.1, 4.1.6, 7.5.6; Process Description: The organization determine which production processes require validation and which processes can be verified during the design and development process. Process validation may apply to processes that generate components, subassemblies, or finished devices. As an examples of processes that require validation label information printing of the AFO line had been audited. The Bellmark printer had been newly implemented.</p> <p>PSC-11 Process Description Control and monitoring procedures include in-process and finished device acceptance activities as well as environmental and contamination control measures. Processes used in production are controlled, monitored, operated within specific limits. Work instructions for assembling are available and final tests are established. Final test reviewed. The cleaning of the cleanroom is conducted by an external service provider. Please see also PSC-2/ PSC-6</p> <p>PSC-12: A training records of external cleaning operators had been reviewed. The hygiene instructions are trained on regular basis.</p> <p>PSC-13 ISO 13485:2016: 7.5.1, 7.6; Process Description: Production and test equipment selected for review is suitable for its intended purpose and capable of giving valid results. Monitoring and measurement devices are defined, calibrated in specific intervals and maintained. The calibration is done internal and external. Dräger has determined the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product</p> <p>PSc-14 ISO 13485:2016: 7.5.1, 7.6; Process Description The measurement equipment is appropriate labeled. An impact analysis of monitoring and measuring device found out of specifications is required according to SOP. Product labels are printed and directly attached to the product.</p> <p>PSC-16 Process Description:</p>

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	<p>The manufacturer has established and maintained a file for each type of device that includes or refers to the location of device specifications, production process specifications, quality assurance procedures, traceability requirements, and packaging, labeling specifications.</p> <p>The manufacturer determined the extent of traceability based on the risk posed by the device in the event the device does not meet specified requirements. DMR is established, DMR is filed in different database solutions, including SAP, e.g. work routing plan per workplace is provided in SAP, work step description can be further explained in further documents, e.g. drawings that are stored in SAP.</p> <p>BRA:</p> <p>Components (e.g. housing, foam) and enclosure have a separate label with their serial number. All these components are documented in the DHR per each device in the ERP System .</p> <p>CAN:</p> <p>All devices are designed to meet the safety and effectiveness requirements of the CMDR. The technical documentation is checked while the regular technical file review according to MDD/ MDR. Additionally the passed final test (see above) makes sure that essential safety aspects are verified. The language is English or symbols are used on the label.</p> <p>US:</p> <p>The device gets a label with the identification number which is also used for the packaging label.</p> <p>All products are clearly identified with labeling with the following minimum information: Part Number, Revision, Lot or serial number, expiration date where applicable and acceptance status. The labeling is maintained throughout the movement of the product within the Dräger facility. A procedure defines that the labeling must be legible, properly adhered and applied to the individual packaging unit to ensure identification and traceability is maintained.</p> <p>PSC-17</p> <p>ISO 13485:2016: 4.2.1, 7.5.1, 7.5.8, 7.5.9.1, 8.2.6</p> <p>Process Description</p> <p>Dräger maintain a record of the amount manufactured and approved for distribution for each batch of medical devices, the record is verified and approved, the device is manufactured according to the specific instructions, and the requirements for product release were met and documented.</p> <p>Brazil:</p> <p>the batch record contains the date of manufacture; components used; quantity manufactured; results of inspections and tests; parameters of special processes; quantity released for distribution; labeling; identification batch of production; and final release of the product</p> <p>US:</p> <p>The label and labeling used for each production lot are documented in the batch record.</p> <p>For the Humidstar 2+LL an example of batch record had been reviewed of the supplier ULAX.</p> <p>PSC-20</p> <p>ISO 13485:2016: 7.5.10;</p> <p>Process Description</p> <p>The organization has implemented controls to identify, verify, protect, and safeguard customer property provided for use or incorporation into the product. The organization treats patient information and confidential health information as customer property.</p> <p>PSC-25</p> <p>Distribution of accessories, including HME and Filter is conducted by Hegele, an external distribution provider, located in Frankfurt.</p> <p>New supplier is Fiege.</p> <p>Distribution records are available in SAP and can be edited on demand.</p> <p>Distribution to Brazil, Japan and Australia had not been performed yet for the Humidstar</p> <p>PSC-29</p> <p>Process Description</p> <p>Based on the assessment of the production and service control process, the management provides the necessary commitment to the production and service control process.</p>
Reviewed documents and records (identification and revision)	<p>Andre Paul, remotely, logistic,</p> <p>Standard process at Dräger:</p> <p>DCMF SC6200 Produktherstellung, Rev.02; 2021-11-21</p> <p>Flow diagram of production from production order to finished products and transport.</p> <p>Other instructions are linked, e.g.</p> <p>DEMF SC6200_A01-de-02</p> <p>Weitere Vorgaben zum Produktionsherstellungsprozess, 2021-11-30</p> <p>SC6110 Handling of Nonconformities in Production</p> <p>Product status has to be identifiable during production</p> <p>AFO line is a continuous production line, feed with raw material, output finished product.</p> <p>In process control: start with random samples, will be inspected by line operator. 100% inspection for leakage, visual, etc.</p> <p>Plan Primär-Planung via Product Manager</p> <p>Planning orders are considered. SAP automatically checks if all raw materials are available. The production order will be released by logistics and shop floor specialist.</p> <p>US:</p> <p>(Stefan Lange) Label UDI:</p>

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	<p>DWAG LM 2132 Object Approval for Labelling Relevant Technical Specification, 2012-05-17 Material specific Transfer of data from development status to production</p> <p>Screenshot: SAP Hejunktakboard for AFO line: production order listed according priority, Partno., order no. production quantity Order no. is unambiguously and given by SAP automatically. Excel sheet Material. 1570081-A1 specification for Humidstar: Datamatrixcode is predefined.</p> <p>Lable UDI: Drawing of 1570081-A1: primary lable: place holder M for datamatrix : GS1 datamatrix code DMS OF5310; GTIN, 1570081-A1 manufacture date; expiry date; LOT Number, serial number, material number reversion. Drawing of 1570081-A1: primary, No. 11203201-00 Clear writing is also available.</p> <p>Document of STED Filter Plus MDR 108-043, Product and packaging label: Label of Humidstar 55+ MP05730, included data matrix code</p> <p>1570081-D: outer packaging for Humidstar 55+ MP05730,</p> <p>Tour of HME / filter production line (AFO):</p> <p>The production of HME and filter is conducted on an automatic production line (A210026), in line are following processes: -assembling of filter /HME, bottom and top housing, foam and filters -ultrasonic welding of top and bottom housing -surface activating of top housing-preparation for printing -printing on top of top housing Control panel: +GLP3_OP1, integrated in production line -Packaging is integrated within production line: Thermoforming foil: -Label print on Tyvek with required label information; The equipment "Multivac" is integrated in the line, the Tyvek lid is sealed on the blister 100pcs in one bag;</p> <p>Drawing MP05735-03 HME Humidstar 25 Plus, released 2022-10-13 Part Specification MP05735-05 HME Humidstar 25 Plus, 2023-03-15 Herstellungsanweisung "Medical Filters" Produktionslinie Medical Filter (Equipment Nr. A210026) Area of production is colour coded: Room no. 1015; 1012 clean room: Assembly and blistering (primary packaging) and secondary packaging (bag), transport packaging is outside the cleanroom</p> <p>Herstellanweisung: Qualitätssicherung "Medical Filter", 2023-02-01 Visual random sampling Nonconforming materials Shelf life Prüfung In process control, which is in-line, and applies 100%: Leakage, resistance, filtration performance, printing At each production change additional tests are conducted. The equipment are dedicated to the calibration process</p> <p>PTS: MP 05798_05 Produktions-und Test Spezifikation für medizinische Atem Filter und HME, 2022-10-14 -Interface of the product: two cones ISO 5356-1) and luer connector acc. 80369-1 Adjusting and test guidelines Definition of test environment Clean room ISO class 8: Environmental conditions: Temp: 5-40°C Humidity 5-95% Ambient pressure : 570-1200hPa</p> <p>Functional test-100%: F-HMR_TSR_555 (EDO : essential design output) Leakage: 11.8ml not more than =>55hPa Resistance check: <0 2ml bei >= 30l/min Cleanliness of products: visual check Acceptance criteria Definition of sampling: per production order and at the start and end of shift, 8 samples are taken for in process control: Visual inspection: Sealing of blister, label printing of Tyvek readable, lint on filter (Cleanliness No visible contamination)</p> <p>Nonconforming products: SC6111 Lenkung von fehlerhaften Material , 2018-11-01</p>

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	<p>Failure analysis/ identify nonconforming products: Identification of non-conforming device Blocking label: blocked Material, separated in blocked area Stock of material will be blocked Special releases: possible with a "Bauabweichung"</p> <p>Handling in case of stock blocking Rework is not applicable</p> <p>Special releases: possible with a Bauabweichung Freigabe einer Bauabweichung FBA 860000003178: Humidstar 55+, MP 05730, Rev.6, from order 65396950 2022-08-25 to 2023-02-01/ released 2022-11-14 Soll: a validated printer shall be used/ IS: new printer was used; process validation is missing Team has defined: DTE1: function not affected. Risk management included: patient and user risk is acceptable. Blister lable printer Validation was done, but no document No influence to intended use, following processes not affected.</p> <p>DMS OF4160-de-105-00 Betreiben von Reinraumprozessen., 2008-04-01 DWAG PQ810 Betriebsmittelüberwachung, Rev. 02, 2023-05-13 _A04 Kennzeichnung von Betriebsmitteln: Date of calibration/ date of next calibration DMS OF4160-de-105-00 Betreiben von Reinraumprozessen, 2008-04-01 Herstellanweisung 11030448-01 Checking the air purity "Medical Filter", 2023-01-05 Klassifizierung der Luftreinheit anhand von Partikelkonzentration, 2023 Reports reviewed: Test report: Particle measuring: 2023-09-15 AFO Reinraum, target class 8, 0 particles are measured Certificate result: passed 2023-09-08: one fail/ Certificate result: failed, Messpunkt 11, 0,5: 3574664 vs 3.520.000 limit exceeded (exceeded limit) In case of exceeded limit: Production stopp/ information to IE (Industrial Engineer) and QE 2023-09-05: one fail/ Certificate result: failed, Messpunkt 12, 0,5: 4.728.834 => please see finding list 2022-12-21: Certificate result: passed, with measures in particle. OIn case of deviation: CFT Cross function team shall be informed; im D&D plan: employee production/ quality engineer/ MRP Controller/ product quality manager.</p> <p>Refer to DCS SC 6110-de-013-000 Behandlung von Abweichung in der Produktion, 2016-07-04 QE shall be informed, limitation and correction. Influence of following processes to be assessed Corrective action shall be defined</p> <p>Bellmark printer (new printer on line AFO) Medical Filter Inhouse Verification and Validation Bellmark printer Protocol: V& V Afo Plan _P_V_V_P A210026 for complete line: reference to initial IQ OQPQ</p> <p>IQ-plan: 101137 Medical Filter Inhouse Process Installation Qualification for line AFO, dated 2023-01-31: Test items defined: Implementation of bell mark printer: Test Item nr. PIQ_09_001 Protocol: IQ OQ PQ</p> <p>Medical Filter Inhouse Verification and Validation Bellmark printer Protocol: IQ OQ PQ Dated 2023-01-31: Bellmark IQ OQ PQ takes place after supplier installation has been performed Test items: IQ_01_001 to 003are defined and checked and passed Test items: OQ_01_001 to 003 are defined and checked and passed Test items: PQ_01_001 to 003 are defined and checked and passed</p> <p>Current production order: FA: 65577935; Mp 05735 Chargen no. 1011552545 Produktmappe Herstellungsprotokoll, shelflife Prüfung, visual inspection of raw material Defected parts Test parameters set up and checked: set up direct online, Content of document file: Change history, special releases, manufacturing instruction, protocol, drawings MP05735-03, 3 lines of raw material (bottom case, top case and foam) are feeding the assembly line.</p>

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Subsystem	Production and Service Controls - #90464 (Revalstraße / HM Filter)
	<p>Top case: plasma-activation, and print – print check via online-camera, Inprocess control station: 1. leakage, 2. resistance, 3. filtration performance</p> <p>Change of shift at 14:00h: Shift operator meeting: Information are transferred regarding Non conformities, deficiencies occurred during the shift Inprocess control at shift change: Shift transfer minutes are documented in Excel schedule: AFO Schichtprotokol, includes date, early and late shift, performance data, filtertyp, Break down lock book: Kinematik failure delta</p> <p>Herr Kötze: Calibration expert The maintenance is responsible to the department "Betriebsmittelbau". Dichtigkeitsmessgerät von der Linie: Prüfmodul 9 DichtigkeitsZED: Kalibrierung: last 2023-06-22 Next 2024-06-22 WK Werks Kalibrierschein: Registriernummer 420658, in House Kalibration: within specification, 2021-10-02 Dräger eigenes Kalibrierlabor: nach 17025; Accreditierungs nr. D-K-15191-01-00-2021-04</p> <p>Cleaning of cleanroom; material lock, persona lock, external service Cleanroom responsible person: Andre Putzer Cleaning training Bockholt External cleaning operators: trained to Hygieneconcept AFO, Prozessschulung; dated 2021-11-29, 12 trainees of company Bockholt and Optima /line manufacturer- for service); and intern operator Offer, 2022-05-19, Bockholt Cleaning activities in cleanroom and cleanroom equipment: Material & personal lock, floor, banks, switches, taster, Outside cleanroom: floor Cleaning agents is listed Cleaning of cleanroom coats: Company elis: chargen documentation for cleaning of cleanroom coats: Particle count acc.to ASTM F51: >= 3Mm/ ft</p> <p>DMS OF4160-de-105-00 Betreiben von Reinraumprozessen, 2008-04-01 Herstellanweisung 11030448-01 Checking the air purity "Medical Filter", 2023-01-05 control of air particle : 2x weekly: reg no. 420575 Aero trak portable particle count, model 9310-02/ 93102106002 Last calibration: 2023-03-14 Certificate of calibration TSI Instruments Ltd Result: in tolerance New Mims is calibration database</p> <p>Batch record Records reviewed: Batch record: Product MP05840; Humidstar 2+LL Outsourced production by ULAX: SP-4.1, for MP05840 Neo Luer Lock First production batch of the device Production dates: 21.08-24.08.2023, Batch no. 2023-08-23 ULAX: Incoming inspection: for MP05843 Supplier: MPV , batch no. plastic housing: 230816, part no. ULAX 00.00.045; PP Bormed Quality control: cert. enclose, 200 sample size: released COC: material bachno. 3170022_532 Related to sepc. MP05843 Rev.04 15mm measuring for all 200 samples Foam: supplier ABC Euro softs Sweden: COC: Order no. 50207/ Product 0-01-015, batch no. 01308355 Order no. for impregnation: Lot 22/207, lsg. MP25441 In process inspection: Batchno. 01308335: weight cal hex. M chlorid Order of Dräger: dated 2023-08-23 Po number TSINB4303102511 Order confirmation for MP05840 3300 pieces Page 2: Material MP05840, shelflife controlled material accord. to DSC SC2090 required COC of finished device: for orderno. 4303102511, traceability of raw material used, inspected and in conformance Label: Inspection of labels: product label and secondary packaging label Humidstar 2+LL primary and secondary label: Lot no. 2023-08-23 DDrägerwerk AG & CoKG Moissliner Allee 53-55 23558 Lübeck US: Draeger Medical Canada Inc 5025 Tuggle Road</p>

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Subsystem		Production and Service Controls - #90464 (Revalstraße / HM Filter)
		<p>Memphis 38118, US Order packing no. unambiguously</p> <p>CANADA: Order packing list: Consignee: Draeger Medical Canada Inc 2425 Skymark Ave Unit Mississauga L4W 4Y6, CA</p> <p>Information listed: -Part no. -quantity -Delivery note, -Batch/ lot</p> <p>Based on the assessment of the production and service control process, the management provides the necessary commitment to the production and service control process.</p>
Names and titles of persons interviewed		<p>Matthias Ahrends, Wertstrom Manager- line Manager including Humidstar Lucie Sander, Quality System Manager; Skipt Alexandre Barette, Quality System Manager for Humidstar Tim Aumann, supplier quality manager, for Filter and Sensor Alexandra Kreymeyer Axel Bürger, Industrial Engineer , technical for line Alex Kühn, Industrial engineer, Verification & Validation, maintenance of equipment, establish of machine Gerrit Meta, Quality engineer, in production Steffen Lange, remote: Label</p>
Products, components, or projects reviewed		See above
Statement concerning conformity based on objective evidence reviewed for this subsystem	<input checked="" type="checkbox"/>	Actions are needed for this process to conform to requirements. See audit finding list.

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2.5.15 Purchasing

Subsystem	Purchasing
Audit trail records of	Pavlov
Area(s) visited (location, e.g., site visited)	Location # 10578 For more details related to Audit location and time refer to chapter 2.2 of this report.
Audit criteria according to audit plan	<p>"Purchasing: Planning Activities Regarding Purchased Products and Outsourced Processes (MDSAP Chapter 7, Task 1, Site: 10578); (DIN)(EN) ISO 13485 - 4.1.2, 4.1.3, 4.1.5, 7.1, 7.4.1, 7.4.2, 7.4.3 + (DIN)(EN) ISO 9001 - 4.4, 8.1, 8.4 + MDSAP - Australia - TG(MD)R Sch1 P1 2, Sch3 P1 Cl1.4(5)(d)(ii) + MDSAP - Brazil - RDC ANVISA 16/2013: 2.5.1, 2.4 + MDSAP - Japan - MO169: 5-2, 5-3, 5-5, 26, 37, 38, 39; [Old: 5, 26, 37, 38, 39] + MDSAP - USA - 21 CFR 820.20, 820.50 + MDR - Article 10.9 ¶3 (d), 10.15; Annex IX 2.2 ¶2 (b3, e); Annex XI 6.2 ¶2 + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2), [EK-MED 3.09B16]"</p> <p>Purchasing: Selection of Supplier File to Audit (MDSAP Chapter 7, Task 2, Site: 10578 "Purchasing: Procedure for the Control of Purchased Products and Outsourced Processes (MDSAP Chapter 7, Task 3, Site: 10578); (DIN)(EN) ISO 13485 - 7.4.1 + (DIN)(EN) ISO 9001 - 8.4.1, 8.4.2 + MDSAP - Australia - TG(MD)R Sch3 P1 Cl1.4(5)(d)(ii) + MDSAP - Brazil - RDC ANVISA 16/2013: 2.5.1 + MDSAP - Japan - MO169: 37 + MDSAP - USA - 21 CFR 820.50 + MDR - Article 10.9 ¶3 (d); Annex IX 2.2 ¶2 (b3); Annex XI 6.2 ¶2"</p> <p>"Purchasing: Extent of Controls Applied to the Supplier and the Purchased Product; Criteria for Selection, Evaluation, and Re-Evaluation of the Supplier (MDSAP Chapter 7, Task 4, Site: 10578); (DIN)(EN) ISO 13485 - 7.4.1 + (DIN)(EN) ISO 9001 - 8.4.1, 8.4.2 + MDSAP - Brazil - RDC ANVISA 16/2013: 2.5.2, 2.5.3 + MDSAP - Japan - MO169: 37 + MDSAP - USA - 21 CFR 820.50 + MDR - Article 10.9 ¶3 (d); Annex IX 2.2 ¶2 (b3); Annex XI 6.2 ¶2"</p> <p>"Purchasing: Selection of Supplier Based on Ability of the Supplier to Satisfy the Specified Purchase Requirements (MDSAP Chapter 7, Task 5, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 7.1, 7.4.1 + (DIN)(EN) ISO 9001 - 7.5.1, 8.1, 8.4.1, 8.4.2 + MDSAP - Australia - As required by MDSAP AU P0002 + MDSAP - Brazil - RDC ANVISA 16/2013: 2.3.3, 2.5.3, 2.4 + MDSAP - Canada - As required by MDSAP AU P0002 + MDSAP - Japan - MO169: 6, 26, 37; [Old: 6, 26, 37, 65] + MDSAP - USA - 21 CFR 820.50(a) + MDR - Article 10.9 ¶3 (d); Annex IX 2.2 ¶2 (b3); Annex XI 6.2 ¶2"</p> <p>"Purchasing: Records of Supplier Evaluation (MDSAP Chapter 7, Task 6, Site: 10578); (DIN)(EN) ISO 13485 - 7.4.1 + (DIN)(EN) ISO 9001 - 8.4.1, 8.4.2 + MDSAP - Brazil - RDC ANVISA 16/2013: 2.5.3 + MDSAP - Japan - MO169: 37 + MDSAP - USA - 21 CFR 820.50(a) + MDR - Article 10.9 ¶3 (d); Annex IX 2.2 ¶2 (b3); Annex XI 6.2 ¶2"</p> <p>"Purchasing: Effective Controls over Supplier and Products (MDSAP Chapter 7, Task 7, Site: 10578); (DIN)(EN) ISO 13485 - 7.4.1 + (DIN)(EN) ISO 9001 - 8.4.1, 8.4.2 + MDSAP - Australia - TG(MD)R Sch1 P1 2 + MDSAP - Brazil - RDC ANVISA 16/2013: 2.5.2, 2.4 + MDSAP - Japan - MO169: 37 + MDSAP - USA - 21 CFR 820.50(a) + MDR - Article 10.9 ¶3 (d); Annex IX 2.2 ¶2 (b3); Annex XI 6.2 ¶2"</p> <p>"Purchasing: Verification of the Adequacy of Purchasing Information, Specified Purchase Requirements, and Written Agreement to Notify Changes, Before Their Communication to the Supplier (MDSAP Chapter 7, Task 8, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 7.4.2 + (DIN)(EN) ISO 9001 - 7.5.1, 8.4.3 + MDSAP - Australia - TG(MD)R Sch1 P1 2 + MDSAP - Brazil - RDC ANVISA 16/2013: 2.4, 2.5.4, 2.5.6 + MDSAP - Japan - MO169: 6, 38 + MDSAP - USA - 21 CFR 820.50(b) + MDR - Article 10.9 ¶3 (d), 10.15; Annex IX 2.2 ¶2 (b3); Annex XI 6.2 ¶2"</p> <p>"Purchasing: Documented Purchasing Information and Specified Purchase Requirements (MDSAP Chapter 7, Task 9, Site: 10578); (DIN)(EN) ISO 13485 - 7.4.2, 7.5.9 + (DIN)(EN) ISO 9001 - 8.4.3, 8.5.2 + MDSAP - Brazil - RDC ANVISA 16/2013: 2.3.3, 2.5.4, 2.5.5, 6.4 + MDSAP - Japan - MO169: 38, 48, 49 + MDSAP - USA - 21 CFR 820.50(b), 820.65, 820.160 + MDR - Article 10.9 ¶3 (d), 10.15; Annex IX 2.2 ¶2 (b3); Annex XI 6.2 ¶2"</p> <p>"Purchasing: Verification of Purchased Products (MDSAP Chapter 7, Task 10, Site: 10578); (DIN)(EN) ISO 13485 - 4.2.1, 7.1, 7.4.3 + (DIN)(EN) ISO 9001 - 7.5.1, 8.1, 8.4.2, 8.4.3, 8.6 + MDSAP - Australia - TG(MD)R Sch1 P1 2, Sch3 1.4(5)(e) + MDSAP - Brazil - RDC ANVISA 16/2013: 2.4, 2.5.2, 3.35.3.1, 5.3.2, 5.3.3 + MDSAP - Japan - MO169: 6, 26, 39 + MDSAP - USA - 21 CFR 820.50, 820.80(b) + MDR - Annex IX 2.2 ¶2 (e); Annex XI 6.2 ¶2 + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>"Purchasing: Purchasing Control Activities as Source of Quality Data for the Measurement, Analysis, and Improvement Process (MDSAP Chapter 7, Task 11, Site: 10578); (DIN)(EN) ISO 13485 - 8.4 + (DIN)(EN) ISO 9001 - 9.1.3 + MDSAP - Brazil - RDC ANVISA 16/2013: 7.1.1.1 + MDSAP - Japan - MO169: 61 + MDSAP - USA - 21 CFR 820.100 + MDR - Article 10.9 ¶3 (m); Annex IX 2.2 ¶2 (b2); Annex XI 6.2 ¶2 + MDD - Annex II (3.2), Annex V (3.2), Annex VI (3.2)"</p> <p>"Purchasing: Top Management Commitment to the Purchasing Process (MDSAP Chapter 7, Task 12, Site: 10578); (DIN)(EN) ISO 13485 - 4.1.3, 4.1.5, 5.2 + (DIN)(EN) ISO 9001 - 4.4, 5.1.2, 8.4 + MDSAP - Brazil - RDC ANVISA 16/2013: 2.2.1 + MDSAP - Japan - MO169: 5-3, 5-5, 11, [Old: 5, 11] + MDR - Article 10.9 ¶3 (c) + MDD - Annex II (2, 3.1)"</p>
Brief description of processes or activities evaluated to demonstrate what was audited related to the listed key QMS documents and records	<p>PUR #1 - Planning activities regarding purchased products and outsourced processes Planning activities regarding purchased products including product acceptance and outsourced processes are established. The established data base system contains relevant information to required documentation / information / acceptance criteria for purchased products/components and related suppliers. Supplier selection and purchasing is described in SOPs. Risk management is part of supplier selection and purchasing.</p> <p>The list of outsourced process is defined and demonstrated during ether audit The list is created as attachment to the Quality Manual CS100.</p> <ul style="list-style-type: none">- The examples of the outsourced process include: Archiving of the documents - Design and development - HR / Training *Fa Skillnet - training process)

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reviewed
below
considering
inputs,
outputs, and
measures

- Service and maintenance - outsourced to the sales and service partner organization
- IT Service – outsourced
- Logistic service - Hegele HealthCare logistics / Simon Hegele (also repackage and relabel, including separates).
- Project handling – outsourced to the own country partners organizations.
- Regulatory roles and service
- Sterilization – Depending on the product)e.g. BGS Betagamma- Gamma service GmbH
- Suppl of finished Medical devices – Category Approval category Z01 according to SP2110
- Clinical evaluation consultant - Quality and regulatory services – Dr. Proff. Imhoff
- Cyber security expert

The structures of the purchasing process is defined in the organization structures, each Business Unit (BU) defines the roles and the leadership for the process of supplier control are defined at the level of Business unit.

The role Lead Byer is defined globally as global for larger supplier, which shall be control at the corporate levels between the BU's.

The commodity managers are responsible for the particular larger material supply such as major plastic and metal suppliers.

The roles for supplier Quality Management, including claims and supplier inspections.
Draeger Corporate Global Guido Willman.

The roles and responsibilities are defined and presented during the audit:
Supplier Quality assurance Therapy
Head of Quality Kevin Dornau

Global commodity Manager (larger suppliers e.g. plastic)

PUR #2 - Selection of supplier file to audit

Following supplier were selected as linkage from management review as suppliers indicated with problems:

- The supplier Global med Canada was listed as the critical suppliers with problems in Management review - High PPM value 597, Flex Hose - (accessories – inspiration devices) – manufacturer Gaelmed
- Supplier Zolner MU26494 – Power supply assembly – High Quality issue spike in Feb 2022
- The clinical consultant Prof Dr. Professor Imhof was selected as critical service provided – consultant service clinical evaluation was chosen as Consultant with impact to the safety and permeance – as link from CER process

There is no Supplier or Consultant from Brazil.

PUR #3 - Procedure for the control of purchased products and outsourced processes.

The supplied categorization is performed as Supplier Phase in and Quality Approval (SP2110), the Categories are defined as Attachment 04.

The examples of categories include:

- ZEX – the material supplier - for Drager Safety division – note relevant
- Z01 – finished medical device (supplied externally)
- Z- materials / components or Treadwear (handlebar)
- ZES - approved materials – Engineers solution – not relevant for medical devices
- ZL - limited material supplier to different reasons, (e.g. quality problems)
- ZS – service parts supplier, which are not as materials for production
- P – approved suppliers for prototypes
- N - disapproved supplier

The categories of the service providers are categorized as following:

- DB- Operations equipment , INCLUDEING PRODUCTION EQUIPMENT AND SERVICES, laboratory equipment,
- DB1 - Operational equipment and materials for production process with high impact for the safety and performance such as Calibration gases, amnesty gases for calibration
- DC Consultants services relevant for product safety and performance [SAP consultants services]
- DE – developments of Hardware and software
- DE-1 – same as DE, however with higher risk class
- DH – human resource services
- DK calibration services
- DK1 – calibration, with requirements for Accreditation

Approval category indicates if the supply categorization would require additional Prioritization according to The Supplier Prioritization SP6250

This is required specifically for the Suppliers categories:

Z01 / Z (depend of product) and DC01 (consultants), DE1 (design with impacts), DK1 (calibration with accreditation) and DL1 (critical logistics)

The Prioritization is performed as a result for prioritization or Criticality of suppliers –

Priorities supplier means Critical but not as defined according to IEC6060

Typical Priorities are:

- P1 – traceability and product class According to GM2150 (requires traceability)
- P2 – components with Breathing gas contact
- P3 – Critical Part according to 60601

Receiving inspection procedure are implemented (DCS SC 5130), the results are documented on individual forms, and in SAP system.

The check of prioritization was performed during the audit based on example:

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The component part MP01061 Expirationventil Einweg valve categorized as critical components for Traceability (exchange of Energy) Ct 50

PUR #4 - Extent of controls applied to the supplier and the purchased product; criteria for selection, evaluation, and re-evaluation of the supplier

Criteria for selection, evaluation and re-evaluation of suppliers are given within procedures and annexes DEMF SP2110, DEMF 2110_A04-en-03.00, DEMF SP625005.05.2023. The Supplier Control criteria documented in DEMF SP2110, are used to define the type and extent of control to be exercised over the product, services, suppliers, consultants and experts.

Suppliers are categorization in different approval category e.g. ZEX approved-supplier of EX material, Z01- approved supplier for finished medical devices, DC -consultants and experts.

KPI are basically splatted to the logistic performance (date reliability, VMI performance) and quality performance (FAI Performance, failure rate performance, ship holds). Based on that KPIs suppliers are classified to:

High performance supplier > 95% to 100 %

Adequate supplier > 75% to 95%

Low performance supplier > 60% - 75 %

Poor performance supplier up to 60%.

Risk categorization of suppliers and service providers and the controls required for a sourced product or service depends on many factors and are reviewed for all suppliers and service providers which are quality relevant. This takes place in separate meetings, as a part of product quality board or as a part of reviewing overall purchasing performance.

The inputs are global/ local supplier quality targets, total failure rates, supplier evaluation planning and results, supplier audits.

Following control were observed for specific examples selected in Task PU-2

Example 1

Prof. Dr. Imhoff – supplier Consultant fir Clinical Evaluation: The supplier is released from 2022

Reapprovals was performed according to reclassification for the supplier 2019 Prof Imhof

The supplier qualification cat DRO according to SPS21

Supplier Questionnaire Service provider for Clinical evaluation 2018-08-13

97506 Disapproval – re-approval of the supplier b

Example 2:

Supplier Zollner (power supply)

96849 First approval Questionnaire Zollner electronic ag, Zandt , Germany - 218-11-2011

CS96849 Production Records - indicated as Traceable Class 40 and 50, the part is relevant for Electrical safety (P3)

The initial approval indicated ISO13485 certification

QMS Certificate 13485:2016 DEKRA - 2024-08-09

Quality agreement - Zollner (power supply) – 17.12.2009

The Quality evaluation is performed twice per year

CS96849 Delivery and Quality Performance evaluation - HY 01/ 2023

Quality issue Zollner

20012551 Supplier Corrective action report Zollner Stecker issue MU26494 28.02.1012

20012551 8D report Zollner Stecker issue

Investigation performed – 100% conformed - corrective action planned

PUR #5 - Selection of supplier based on ability of the supplier to satisfy the specified purchase requirements

The requirement for the suppliers are defined per supplier's category listed in A04 attachment for SP21110,

The evaluation Plan is established for the year.

For example, for clinicals consultant – Category DRO – requirement is Attachment 08 Service Provide for clinical evaluation. The attachment is sufficiently covering specific requirements for the clinical consultant

The Framework Agreement Supplier Dr Prof Imhoff - 14 par 2016

The supplies is notes as supplier with prior station - a continuous supplier control:

The supplier from Priorities list undergoes annual evaluation according the Supplier evaluation Tool GoBench (process SP6110).

Delivery and Quality Annual evaluation : Prof Imhof : 19.09.223

CS97506 Supplier Dr Imhof -- evaluation result 100%

Criteria – single expert person: CV / Scientific record - demonstrated

CV – Prof Imhof – Clinical consultant Stand 31.05.2018 - demonstrated

Response rate for the supplier 100%

Agreed supplier Evaluation Plan 2023 – 12 Jun 2022

The plans show, who and when is responsible for periodical evaluation, Lead Commodity category, PPM and if evaluation is applicable.

Example II

MP00303 Hose system Anesthesia set Flex latex free

Supplier Complete set (Finished Medical device) Gaelmed Corporation (China) – category Z01

94676 Supplier data card SAP Gale Med Corporation Taiwan

116761 Supplier Gale Med China – production Factory

The Row Hose supplied from Globalmed Canada

Supplier approval: for category Z01 (supplier of finished Medical) following documents are required: requires SP2110 Attachment A10 and Attachment Supplier A09, the reapproval is documented on the Supplier Approval sheet A01

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DEMFP2110 A09 – additional supplier questionnaire for Contract manufacturers /developers: Rev 01
The shall be agreed by Quality, Product owner and Supplier Quality
In the approval sheet is signed
DEMFP2110_A01 Supplier approval sheet Ver 04 (Form)
Supplier approval -
DEMFP2110 AA Rev 00 Supplier requirements for Finished medical devices 2019-04-01

The Supplier Gaelmed was approved - 08 August 2016, according to the legacy process SP2010, Attachment 1
Gaelmed Xiamen (116761) The supplier Questioner and Approval card - 08 August 2016
Australia
Supplier is certified by TUV Rhineland to ISO13485
The supplier Category station is performed
Supplier categorization table CS94676 Gaelmed Xiamen
Categories Z01, Breathing Gas Contact and Traceable and
CS94676 Gaelmed Xiamen Supplier prioritization record

Supplier evaluation requirements demonstrated from List of prioritizations of suppliers:

- ISO 13485 Active control
- DQPE
- QAA

Supplier evaluation records:

ISO 13485 certificate from TUV Rhineland – Gaelmed Xiamen - valid 2024-06-21
ISO 13485 certificate from TUV Rhineland – Gaelmed Taiwan – valid 2023-12-28
CS94676 Gaelmed Xiamen Supplier Delivery and Quality performance HY 02/2022 -
CS94676 Gaelmed Xiamen Supplier Delivery and Quality performance HY 01/2023

PR 123501 Vendor assessment report Gaelmed Taiwan - 09 Nov 2022
PR 121516 Vendor assessment report Gaelmed Xiamen - 22 Sept 2022
Quality assurance agreement Gaelmed Corporation Taiwan 27.05 2011
The agreements have included the requirement for Change contra and approval from Draeger

Supplier Audits – is defined as apart of initial approval.

The supplier audits requirement is defined in

The supplier audit report was shown for the supplier Gaelmed Taiwan

The audit report for 2023 was demonstrated – detailed report present, 7 recommendation, 1 minor Finding,

The Auditor Jan Paulsen

The audit report supplier - Gaelmed Xiamen was demonstrated 22 Sept 2022
Lead Auditor Wang, Min; No Findings, 2 recommendations.

Special Country requirements

Australia (TGA):

The registered Sponsor is Draeger Australis PTY , Noting Hill. Vic 3168 Australia

The Distributor agreement – contains the responsibility of the Australian sponsor
Distributor Agreement Draeger Australia PTY 10.08.2018.

Japan (MHLW):

The MAH for Japan is Draeger Japan LTD

The Distributor Agreement Draeger Japan 27 may 2019

The Facility registration was demonstrated: 13B1X00173 from 2-13-17

Brazil,

The representative in Brazil is Draeger Industria e Comercio Ltd, Centre Empresarial tambore 06460-100 Sao Paulo ,
Brazil

The Agreement with the Brazilian regulatory representative was demonstrated:

Distributor agreement Draeger Brazilia – 52/08/2018

Canada:

Draegerwerk AG&Co Company ID 103279 , The regulatory corresponded registered Mr. Mebius from Draeger Germany,
Canada renewal conformation by the letter from health Canada: 2022-11-09

PUR #6 - Records of supplier evaluation

REF to Task PUR 4 for the supplier evaluation records for

- Gaelmed Corporation (China) / Gaelmed Xiamen

- Prof Dr. Imhoff – Quality Consultant for clinical evaluation

Additionally, the auditor has assessed investigation of supplier quality issues for Gaelmed

The follow up in relation to supplier quality issue was performed as part of this audit.

The Supplier Gaelmed Xiamen – manufacturer has identified contamination (white particles) inside the breathing hose:

Demonstrated as 8D report

The issue was highlighted by the manufacturer of the Tube set Gaelmed - communicated via Email in July 2022 as
telephone conference and email from Gaelmed to Draeger

The Corrective action:

1) cleaning of the instrument every 4 hours

2) Run DOE (design of experiment) – validated new process window

3) Installation of Temperature Gages – for the extrusion temp of the process media am nozzle

The Corrective action completed on 07 January 2023

MDR 2017/745 – Article 11(2)

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Authorized representative accepted its designation in writing, and it is effective at least for all devices of the same generic device group –

The Contract for legal -Draeger Medical systems Inc, USA

The agreement demonstrated:

Agreement Draeger Telford USA and Drägerwerk AG Lübeck Germany 24 Jan 2019

PUR #7 - Purchasing

The re-evaluation of the capability of suppliers to meet specified requirements is performed with the significance of the product on the finished device. Re-evaluation is performed with the same system as initial evaluation.

REF to Task 4 for detailed description and examples

PUR #8 - Verification of the adequacy of purchasing information, specified purchase requirements, and written agreement to notify changes, before their communication to the supplier

It could be verified that Draegerwerk assures the adequacy of purchasing requirements for products and services that suppliers are to provide, and defines risk management activities and any necessary risk control measures.

This is ensured by Approved Drawings, Incoming Goods Inspections Test Plan,

Einkaufsrahmenvertrag, Quality Assurance Agreement.

QSVs are needed at least in cases if Supplied Parts are to be traceable.

Approval of DRÄGERWERK is required especially in Change Cases that affect Safety and Reliability, Conformity with Regulatory and Technical Standards, Form, Fit, Function and Labelling.

Purchase orders are approved by the designated Material Resource Planner electronically supported and digitally signed, including date and signature.

The requirements re defined as product specification and optionally as adoption of e QMS from Draeger by the suppliers.

Example: verification of relevant information was performed for finished device (accessory) Anesthesia Set latex free

The purchasing requirements are documented in PLM ARAS system

MP00303 10 ARAS production drawing Ver 09 2020-10-22

MP00303 10 ARAS Part specification Anesthesia Set latex free 2020-11-09

Brazil:

The purchase orders are approved by a designated person with electronic signature in SAP system

PUR #9 - Documented purchasing information and specified purchase requirements

Verified that the medical device organization documents purchasing information, including where appropriate the requirements for approval of product, procedures, processes, equipment, qualification of personnel, sterilization services, and other quality management system requirements.

It also was confirmed that documents and records for purchasing are consistent with traceability requirements where applicable.

Example: assessment was performed in relation to plastic hood for part for Babyleo TN500 incubator and a radiant warmer – it was verified that the degassing process is performed for hood in production: The Part drawing was requested and demonstrated during the audit.

Production Drawing Hood Complete Part 2 M60010 156.01.2020

Degassing process is defined as 180min at 80C

PUR #10 - Verification of purchased products

It could be confirmed that the verification (inspection or other activities) of purchased products is adequate to ensure specified requirements are met.

Further it could be confirmed that DRÄGER has implemented an appropriate combination of controls applied to the supplier, the specification of purchase requirements, and acceptance verification activities that are commensurate with the risk of the supplied product upon the finished device.

Verified that records of verification activities are maintained.

Example was verified in relation to the part sampled during the audit of production floor for Babyleo TN500 incubator and a radiant warmer. Records of successful inspection demonstrated as following:

Example observed for the Part 368451 The test protocol incoming inspection Part 8421200

N 3 parts were checked from overall 192 incoming batch.

Brazil is covered.

PUR #11 - Purchasing control activities as source of quality data for the measurement, analysis, and improvement process

The periodical process for the quality review according to the defined process, the example was demonstrated for BU TH, the process is defined DEMF 1010, the BU has identified specific requirements, each commodity is looked at twice a year according to the requirements defined in Purchasing and supplier Quality control review Definition BU Therapy Sept 2022

PUR #12 - Top management commitment to the purchasing process

Based on the observed example and process, Top Management has demonstrated commitment to the Purchasing process

Reviewed documents and records (identification and revision)

Quality Manual CS100.

List of outsourced process Rev 07 2023-08-25

BU Therapy Commodity review M2 (PCBA units Quality) Septembers 20223

DCS SC5120-en-013-02.00 Incoming Inspection Planning

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	<p>DWAG CS1000-de-08.00, 2023-05-01 DWAG CS1000- The Quality manual - including attachment for outsourced processes</p> <p>DEMF SP2110 : Supplier Phase in and Quality Approval DEMF SP2110 - en - 03.00 , Rev. 03.00</p> <p>DEMF SP2110 : Supplier Phase in and Quality Approval DEMF SP2110 Attachment A04 – approval categories Ver 3</p> <p>DEMF SP2210 : Supplier Audits DEMF SP2210 - en - 02.00 , Rev. 02.00</p> <p>DEMF SP6110 : Supplier Evaluation DEMF SP6110 - en - 04.00 , Rev. 04.00</p> <p>DEMF SP6210 : Supplier Control Risk Analysis DEMF SP6210 - en - 01.00 , Rev. 01.00</p> <p>DEMF SP6250 : Identification and Control of Prioritized Suppliers DEMF SP6250 - en - 03.00 , Rev. 03.00</p> <p>DWAG OF3310 : Control of Standards - with Respect to Suppliers DWAG - OF3310 - en - 00 , Rev. 0</p> <p>DWAG SP2120 : Disapproval, Limitation and Reapproval of Suppliers DWAG - SP2120 - en - 00.00 , Rev. 00.00</p> <p>GM2150 Traceability of products and components V03</p> <p>Purchasing and supplier Quality control review Definition BU Therapy Sept 2022 defines</p> <p>DEMF 1010 rev 2 Quality control loops (used for Quality Control review)</p> <p>DEME GM1250 Checklist Traceability Product and components V03</p> <p>MP01061 Categorization record Expirationventil Einweg valve categorized as critical components</p> <p>Supplier Questionnaire Service provider for Clinical evaluation 2018-08-13</p> <p>97506 Disapproval – re-approval of the supplier bs</p> <p>20012551 Supplier Corrective action report Zollner Stecker issue MU26494, 28.02.1012</p> <p>20012551 8D report Zollner Stecker issue</p> <p>TThe Framework Agreement Supplier Dr Prof Imhoff - 14 par 2016</p> <p>CV – Prof Imhoff – Clinical consultant Stand 31.05.2018</p> <p>Supplier evaluation records:</p> <p>ISO 13485 certificate from TUV Rhineland – Gaelmed Xiamen - valid 2024-06-21</p> <p>ISO 13485 certificate from TUV Rhineland – Gaelmed Taiwan – valid 2023-12-28</p> <p>CS94676 Gaelmed Xiamen Supplier Delivery and Quality performance HY 02/2022 -</p> <p>CS94676 Gaelmed Xiamen Supplier Delivery and Quality performance HY 01/2023</p> <p>PR 123501 Vendor assessment report Gaelmed Taiwan - 09 Nov 2022</p> <p>PR 121516 Vendor assessment report Gaelmed Xiamen - 22 Sept 2022</p> <p>Quality assurance agreement Gaelmed Corporation Taiwan 27.05 2011</p> <p>Supplier Audit report Gaelmed Xiamen was demonstrated 22 Sept 2022</p> <p>200161146 MP00303 8D report Investigation Supplier quality – breathing hose contamination 20/12/2022</p> <p>Production Drawing Hood Complete Part 2 M60010 156.01.2020</p> <p>Purchasing and supplier Quality control review Definition BU Therapy Sept 2022 defines</p> <p>DEMF 1010 rev 2 Quality control loops (used for Quality Control review)</p> <p>PUR Commodity dashboard V10 – quality</p>
Names and titles of persons interviewed	<p>Guido Willmann, Leiter Strategischer Einkauf BU Therapy</p> <p>Timo Harms, QAA Business Unite HCA incl Supplier Quality</p> <p>Jochen Förster-Adler, Supplier Quality manager</p> <p>Tobias Vieth, (Supplier Quality Manager, Therapie)</p> <p>Jan Paulsen (Supply Quality Manage, HCA c(Hopital consumabales)</p> <p>Jochen Foerster-Adler, Supplier Quality, Indirect beschaffung</p>
Products, components, or projects reviewed	<p>See above</p>
Statement concerning conformity based on objective evidence reviewed for this subsystem	<p><input checked="" type="checkbox"/> This process is effectively implemented and conforms to requirements.</p> <p><input type="checkbox"/> Actions are needed for this process to conform to requirements. See audit finding list.</p>

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2.5.16 Cyber Security

Subsystem	Cyber Security
Audit trail records of	Gabriele Mousset with Somesh Rasal (deputy Expert for Jan Küffner)
Area(s) visited (location, e.g., site visited)	Location # 1 For more details related to Audit location and time refer to chapter 2.2 of this report.
Audit criteria according to audit plan	MDR 14.2 (d) IT security
Brief description of processes or activities evaluated to demonstrate what was audited related to the listed key QMS documents and records reviewed below considering inputs, outputs, and measures	<p>Responsibility and authority for cyber security is documented and communicated appropriately as seen in audit. Personnel is competent based. On training, skills (Software Engineering and forensics specialist) and experience (Medical device development) as verified during audit. During audit it was noticed that the same person leading development as well as security for the product</p> <p>During audit it was verified, that security risk management was done at an early stage as seen in the audit.</p> <p>They use ERNW as an outsourced penetration laboratory. Few components like USB, etc., were not part of testing scope as seen in the audit.</p> <p>STRIDE (manual approach) was used as threat modelling technique as seen in the audit.</p> <p>The sampled technical documentation (Atlan A350) provided evidence of appropriate penetration testing. Product undergoes through Penetration testing for every major release.</p> <p>The sampled TDs (Atlan A350) provided a list of SOUP components.</p> <p>The SOUP components are regularly discussed (at least once in a month) if they need corrective actions.</p> <p>During audit it was noticed that documents are managed using Configuration Management rather than document control. Hence, document numbers mentioned below section are reference numbers to documents.</p>
Reviewed documents and records (identification and revision)	<ol style="list-style-type: none">1. Atlan SW 2.00.02 - Threat Analysis.pdf - TA_A3x0_MDR Rev 1 – Signed on 25-1-2023.2. Atlan A350 - Pentest Report.pdf – E20209046 – Created on June 22, 20213. Atlan 2.00.02 Software bill of material.pdf - SBOM_A350_2.00.02 Rev 13 – Created on 13-9-2023.4. Atlan SW 2.0n Cybersecurity maintenance and patch management.pdf - PMP_A3x0 Rev 11
Names and titles of persons interviewed	Mike Neumann
Products, components, or projects reviewed	Software Engineer and Product Security Engineer
Statement concerning conformity based on objective evidence reviewed for this subsystem	<p><input checked="" type="checkbox"/> This process is effectively implemented and conforms to requirements.</p> <p><input type="checkbox"/> Actions are needed for this process to conform to requirements. See audit finding list.</p>

2.5.17 STB assessment of cleaning instruction (Atlan)

Subsystem	STB assessment of cleaning instruction (Atlan)								
Audit trail records of	G. Pavlov								
Area(s) visited (location, e.g., site visited)	Location # 1 HQ: Moislinger Allee For more details related to Audit location and time refer to chapter 2.2 of this report.								
Audit criteria according to audit plan	MDR Regulation EU 2017/745 (MDR); ANNEX I, III 23.4. Information in the instructions for use ISO 17664-1:2021 / 17664-2 Edition 2021 IEC 60601-1:2020, Edition 3.2 Clause 7.9.2.12 Cleaning, Disinfection and sterilization								
Brief description of processes or activities evaluated to demonstrate what was audited related to the listed key QMS documents and records reviewed below considering inputs, outputs, and measures	<p><u>Claims</u> Following statement is document in the Marketing Brochure: Infection Prevention and Control Breaking the chain of infection and complying with your hospital's hygiene protocols is critical in today's clinical environment. For this reason, during the development phase of Atlan anesthesia machines, we designed them with infection prevention regulations in mind to support hygiene measures in the OR. – Tool-free and quick disassembly of breathing system with few parts to be compliant with infection prevention regulations – Smooth and rounded surfaces ease cleaning/wipe disinfection – Cable ducts and channels reduce number of potential contamination sources – Compatible with original Dräger single-use consumables support hygiene standards – Generated message* reminds personnel about the replacement of the RFID technology-based consumables (Infinity ID breathing circuit, Infinity ID WaterLock 2 water trap, Infinity ID flow sensors, Infinity ID CLIC absorber) when their maximum period of use are exceeded – Compliant with ISO 17664</p> <p><u>Provision of Information for Use on Reprocessing</u> It was verified that reprocessing instructions include in validated reprocessing method were included in the Labeling / Instruction for Use</p> <p>For Rev 1.0 Instruction for Use Ver SEW-1.0 –formation for reprocessing was included in the IFU directly For Rev 2.0 Instruction for USE Anesthesia workstation Software 2.0n – info on reprocess was removed from main IFU and included in the dedicated Information on reprocessing is now included in standalone reprocessing Instruction for Use (9510631_1_en)</p> <p><u>Identification of criticality of reprocessing</u> According to Reprocessing Instruction, following classification defined:</p> <table border="1"> <thead> <tr> <th>Classification</th><th>Explanation</th></tr> </thead> <tbody> <tr> <td>Non-critical</td><td>Components that come only into contact with skin that is intact</td></tr> <tr> <td>Semi-critical</td><td>Components that carry breathing gas or come into contact with mucous membranes or pathologically altered skin</td></tr> <tr> <td>Critical</td><td>Components that penetrate skin or mucous membranes or come into contact with blood</td></tr> </tbody> </table> <p><u>Identification of parts subject for reprocessing</u> The following classification is a recommendation from Dräger.</p> <p><u>Non-critical</u></p> <ul style="list-style-type: none"> – Device surfaces <p><u>Semi-critical</u></p> <ul style="list-style-type: none"> – Breathing system – Housing (lower part and upper part) – Inspiratory port – Expiratory port – APL valve – Inspiratory valve (yellow) – Expiratory valve (blue) – Fresh-gas decoupling valve (black) – Absorber container and absorber insert – Sensor cap of the O2 sensor1) – Piston diaphragm – Breathing bag arm (option) <p><u>Critical</u> The device does not contain any components that are classified as critical.</p>	Classification	Explanation	Non-critical	Components that come only into contact with skin that is intact	Semi-critical	Components that carry breathing gas or come into contact with mucous membranes or pathologically altered skin	Critical	Components that penetrate skin or mucous membranes or come into contact with blood
Classification	Explanation								
Non-critical	Components that come only into contact with skin that is intact								
Semi-critical	Components that carry breathing gas or come into contact with mucous membranes or pathologically altered skin								
Critical	Components that penetrate skin or mucous membranes or come into contact with blood								

Overview of the reprocessing procedures of the components

Components	Surface disinfection with cleaning	Machine cleaning with thermal disinfection
Device surfaces	Yes (see "Surface disinfection with cleaning", page 21)	No
Upper part of the breathing system and lower part of the breathing system	No	Yes (see "Upper part of the breathing system", page 25)
Inspiratory port and expiratory port	No	Yes (see "Inspiratory port and expiratory port", page 26)
– Inspiratory valve (yellow)	No	Yes (see "Inspiratory valve, expiratory valve, and fresh-gas decoupling valve", page 27)
– Expiratory valve (blue)		
– Fresh-gas decoupling valve (black)		
Sensor cap of the O ₂ sensor ¹⁾	No	Yes (see "Sensor cap of the O ₂ sensor", page 26)
Absorber container and absorber insert	No	Yes (see "Absorber insert", page 28)
Piston diaphragm	No	Yes (see "Piston diaphragm", page 28)
APL valve	Yes ²⁾	Yes (see "APL valve", page 26)
Breathing bag arm (option)	Yes ²⁾	Yes (see "Breathing bag arm (option)", page 27)

Indication of the reprocessing process for related parts

- a) Surface disinfection with cleaning – Device surfaces

Components	Surface disinfectant	Manufacturer	Concentration	Contact time
Device surfaces	Dismozon plus	Bode Chemie	1.6 %	15 min

The validation of the device service cleaning was not assessed in the audit as low risk and not directly relevant to safety and performance of the device. The recommended chemical for surface cleaning were widely available and listed by national Guidance documents.

- b) Machine cleanable parts

Step	Medium	Manufacturer	Concentration	Temperature	Contact time
Cleaning	MediClean forte	Dr. Weigert	Min. 0.30 %	Min. 55 °C (131 °F)	Min. 10 min
Neutralizing	Neodisher Z	Dr. Weigert	Min. 0.1 %	Tap water temperature	Min. 1 min
Flushing	Demineralized water	–	–	Tap water temperature	Min. 1 min
Disinfecting	–	–	–	Min. 90 °C (194 °F)	Min. 5 min
Drying	–	–	–	–	Drying time depends on the load

The machine decontamination in washer-disinfector observed during the audit is widely acceptable standard washer-disinfector cycle with A0>3000 (high level disinfection)

Validation / verification of the reprocessing procedure

Two validation documents were demonstrated during the audit. Validation was performed in Miele Washer-disinfector, using the decontamination cycle and process chemicals as recommended in the Reprocessing Instruction.

Two documents were demonstrated during the audit:

- 1) Cleaning Efficacy for the representative parts from the breathing circuit –
Test soil used – BCA Protein Assay KIT from Thermo Scientific
Pass Criteria used
Residual protein < 6,4 pg pro sq. cm of tested surface

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	<p>Residual carbohydrates <12 mkg per sq. cm</p> <p>The application of the test soil – documented, seems to be chosen based on risk for most difficult for cleaning – observed on photo documentation in the validation report</p> <p>The result of the report – all values within the defined levels.</p> <p>Record presented: Fachhygienische Stellungnahme zur chemischen Validierung der maschinellen Reinigung verschiedener Komponenten Anästhesiegerät „A350 28. Dezember 2018</p> <p>2) Microbiological test – the investigation for the count reduction $>10^{-6}$ as required for High-level disinfection $A0=3000$</p> <p>The selection and characterization of the test microbial cultures discussed – and documented, selection was performed in line with recommendation of US-Norm ASTM E 18376, US-Guideline</p> <p>AAMI TIR 124 and FDA-Guidelines, taken into account area of application (breathing pathways / lungs).</p> <p>Pass results are documented></p> <p>Record presented: Fachhygienische Stellungnahme zur mikrobiologischen Validierung der maschinellen Desinfektion verschiedener Komponenten Anästhesiegerät „A350“28. Dezember 2018</p> <p><u>Competency of the validation SMEs</u></p> <p>The validation documentation consists of Professional Statement reports prepared by third party: Report authored by Dr. med. Arne Martensen, Facharzt für Hygiene und Umweltmedizin Facharzt für Mikrobiologie, Virologie und Infektionsepidemiologie;</p> <p>im Auftrag der: BZH GmbH Deutsches Beratungszentrum für Hygiene Schnewlinstr. 4</p> <p>The test / experimental part was performed by Herrn Dr. Andreas Sammann, Institut für Hygiene und Umwelt Hamburg, durchgeführt (durch die Deutsche Akkreditierungsstelle DAkkS GmbH gemäß DIN EN ISO/IEC 17025 akkreditiertes Prüflabor, Akkreditierungsnummer D-PL-14095-03-02).</p> <p>The competency of the parties performed the validation is relevant for the performed validation</p> <p><u>Result of assessment during this audit</u></p> <p>The demonstrated Professional Statement (Fachhygienische Stellungnahme) from BZH GmbH (Deutsches Beratungszentrum für Hygiene) does not fully meet the requirements of ISO15883 / ISO 17664-1:2021 / 17664-2:2021.</p> <p>Nevertheless, the methodology, criteria for validation and the tests performed can be regarded as state of the art commensurate to the area and criticality of application taking into account:</p> <ol style="list-style-type: none">1) Standard widely used methodology for machine reprocessing of reusable medical devices – thermo-disinfection with standard cycle and $A0=3000$2) Widely used chemicals for cleaning and neutralization, also recommended by manufacturer of washer-disinfector.3) The Validation used methods generally accepted in ISO15883-14) The fact the reprocessed parts are not invasive and in normal not coming with blood and tissues of the patients. <p>The cleaning instruction was found in line with verified reprocessing methods</p>
Reviewed documents and records (identification and revision)	<p>Marketing Brochure Atlan atlant-a300-a300xl-pi-9107089-en-master 9056001_05_en IFU Atlan A300, A300 XL, A350, A350 XL Anesthesia workstation Software Ver 1.0</p> <p>9510601_1_en IFU Atlan A300, A300 XL, A350, A350 XL Anesthesia workstation Software Ver 2.0</p> <p>9510631_1_en Reprocessing instructions Atlan A300, A300 XL, A350, A350 XL</p> <p>HRSR_SCALA AtlanA3X0 Hygienic Summary report 2022-06-21</p> <p>REF163_sc_2018-12-28_A350 Semikritisch_DES_18-00242-AU001_exVal</p> <p>REF162_sc_2018-12-28_A350 Semikritisch_REI_18-00242-AU001_exVal</p>
Names and titles of persons interviewed	<p>Jens Köhne, Malte Zeuner, Jan Dannemann, Anna-Lena Brüggemann, Stefan Thal, Dirk Zumtobel</p> <p>Jens Köhne Programm Manager</p> <p>Jan Dannemann, System Engineering, R&D Perioperative Care, BU Therapy</p> <p>Stefan Thal, System Product Manager Infection Prevention & Control</p> <p>Dirk Zumtobel, "Head of Test Laboratories, Quality & Regulatory Affairs</p>
Products, components, or projects reviewed	<p>Atlan A300, A300 XL, A350, A350 XL Anesthesia workstation</p>
Statement concerning conformity based on objective evidence reviewed for this subsystem	<p><input checked="" type="checkbox"/> This process is effectively implemented and conforms to requirements.</p> <p><input type="checkbox"/> Actions are needed for this process to conform to requirements. See audit finding list.</p>

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2.5.18 Technical Documentation Assessment

Subsystem	Technical Documentation Assessment EC-Directives
<input type="checkbox"/>	The auditee is not a legal manufacturer of class IIa and IIb devices according to MDD 93/42/EEC and therefore does not maintain technical documentation, which needs to be assessed.
<input checked="" type="checkbox"/>	The auditee is not a legal manufacturer of annex II list B and / or self-testing devices according to IVD 98/79/EC and therefore does not maintain Technical Documentation, which needs to be assessed.
<input checked="" type="checkbox"/>	The sampling plan and log contains detailed information about the manufacturer's technical documentation of MDD 93/42/EEC class IIa and IIb devices, IVD 98/79/EEC annex II list B and self-testing devices and the examples audited.

Refer to the table below for referenced applicable documents for attached TDARs.

Subsystem	Technical Documentation Assessment EU Regulations
<input type="checkbox"/>	The audited organization is a not legal manufacturer according to a European Regulation and therefore does not maintain technical documentation, which needs to be assessed by a Notified Body.
<input type="checkbox"/>	The audited organization is legal manufacturer according to a European Regulation, but product classification does not require Technical Documentation Assessment by a Notified Body.
<input checked="" type="checkbox"/>	The audited organization is a legal manufacturer according to a European Regulation and product classification requires sampling for Technical Documentation Assessment by a Notified Body. The Notified Body maintains a Sampling Plan and Log (MDR Annex IX, 2.3/3.5 / IVDR Annex IX, 2.3/3.5) for internal use, which contains detailed information about the organizations technical documentation assessment (TDA) planning according to applicable European Regulation, the selected devices and the examples audited. This document also contains the Log for assessment history including a justification for sampling.
<input checked="" type="checkbox"/>	For technical documentation assessment based on MDR / IVDR The auditee has submitted all required "Periodic Safety Update Reports" (PSURs according MDR article 86 / IVDR article 81) and if indicated other reports like an update of "Summary of Safety and Clinical Performance" (SSCP) according MDR article 32 and update of "Summary of Safety and Performance" (SSP) acc. to IVDR article 29 to the Notified Body.

Refer to the table below for referenced applicable documents for attached TDARs.

- ☒ This audit report package includes following technical documentation assessment result(s) (TDARs) including involved expert assessment results / attachments, if applicable.

TDAR #	Device name and REF	TÜV SÜD order number	TDAR Date
1	CS-hoses	0713315041	PSUR ongoing
2	TN500	0713315029	TDA ongoing
3	Core Software 1.x	0713315091	TDA ongoing
4	VentStar	0713315096	TDA ongoing

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2.6 Areas not audited although within the original Audit scope

- ☒ All areas / processes from the planned audit scope as defined in the audit plan were audited.
- ☐ The audit was not conducted as scheduled in the audit plan. Followings were skipped or Audit was not sufficient:

2.7 Obstacles encountered, reliability of the Audit

- ☒ There were no obstacles encountered or unresolved issues, if identified, that could comprise the reliability of the audit findings and conclusions.
Documents, records, and qualified answers were available within a reasonable amount of time. The Audit was conducted within the timeframe scheduled in the audit plan.
The Information and Communication Technology (ICT) methods described in the audit plan were employed effectively throughout the audit.

2.8 Verification of effective implementation of corrective action(s) from the previous Audit

The Audit Team evaluated all measures related to the nonconformities from the previous audit(s). The audit team verified that all measures were effectively implemented as planned. The implementation and effectiveness of the measures were followed up by the company using their internal processes.

- ☒ N/A, no nonconformities during previous requiring a follow-up
- ☐ Below is a summary of the evidence reviewed to verify the effectiveness of the implemented actions for the nonconformities from the prior audit(s).
 - (Please specify or refer to the section of this report that's addresses the follow-up of previous conformances)
 -
 -
- ☐ The Audit Team was not able to close all nonconformities from the previous audit(s). See new finding number(s):

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2.9 Conclusion for Action Items derived from various sources (e.g. source TÜV SÜD CBW)

Action items derived from various sources were considered and closed as follows:

CRT Action Item Dräger FSCA ICM PR126573, TPS ID VM63012:

“The investigation confirmed that when ICM is used in combination with a syringe pump connection, under certain under certain conditions, ICM may show entries in the daily curve that were not deliberately created by the user. These entries cannot be edited or deleted by the user. If these additional entries unnoticed, this can lead to inaccurate documentation of prescriptions or previous treatment in the program. Program and thus potentially lead to incorrect treatment decisions.”

Action Item: “Since the Cause of the behaviour has been identified, please review the rationale for not updating the affected systems, considering the principle of integrated safety”.

During audit, manufacturer provided updated information on that case and behavior. This behavior has been changed in the next regular release of the Software (V14) and in Bugfix Version (V 13.02, released 07/2023). Therefore, the requested rationale is not needed anymore.

The Bugfix Version will be rolled out with a new Field action (see “Decision and Order”)

Background Information (as communicated to BFARM 2023-08-08):

- ICM is used by customers in 5 different Software Versions (V9-V13).
- Bug fixing was available with V13.02 (available since 07/2023) and V14.
- Installation of V12 + V13 are technically updateable to 13.02; however, this involves a high effort withing hospitals, since the IT infrastructure is involved; therefore, Dräger forecasts this update to take around 12-months' time.

The problem described within FSCA can only happen in installations that use the option “Syringe Pumps Connection”; this connection is only be used by very few customers. Dräger will approach customers with these versions in order to either update to V13.02 or to deactivate the option causing the issue.

Records for this case:

Competent Board Decision 2023-01-13

Specific Risk Assessment RM CAPA PR123704-signed.pdf

TSB_4_ICM_Decision and Order_signed.pdf 2023-08-01

„13.02 ist verfügbar“ Release Notes ICM Patientenmanagement Software 13.02 6495.525_de, versendet 2023-07-28

Kundeninformationsschreiben im Entwurf vorhanden (...), wird noch im September versendet.

eMail 2023-08-08 to Competent Authority Landesamt für soziale Dienste Schleswig-Holstein

PR123101 Decision Closure Report 2023-09-19

Jira-Defect Entry Ticket ICM-13149

Jira-Defect Entry Ticket ICM-13254 – for V13.02 – 1306887 Test case 13254: Approved, Passed

RQM Test case 114863

SW-release-No mt-1622 Prt-No. MK0517103 for V13.02

ICM Customer letter Fluid Management Deutsch update _final.pdf (2023-09)

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3 Events, changes, follow-up, action items

3.1 FSCA/FSN, Recalls, Product Removals, Replacements, other Vigilance Information

See subsystem "Device Adverse Events and Advisory Notices Reporting, Post Marketing Surveillance and Vigilance system".

3.2 Substantial / Significant Changes Since the Last Audit

Reported Changes	Change Notification Number (if applicable)	Verification (if applicable)
none	none	<input type="checkbox"/> Prior to Audit <input type="checkbox"/> During audit

The auditee(s) must notify the TÜV SÜD project handler of all significant and substantial changes to the approved quality management system and device-range covered by the certificate(s) before implementing changes.

3.3 Audit Program Status

An update of the audit program was not necessary.

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4 Conclusion, Final Summary and Recommendation to the Notified Body / Certification Body

4.1 Multi-Site / Facility Audit

- ☐ Not applicable
- ☒ Audit Team as listed on page 1 conducted the audit at all sites / facilities within the scope of certification. No further conclusion necessary.
- ☐ See audit report for site / facility [enter site if applicable] (Head Quarter) for Synthesis Report Information.

4.2 Audit Team recommendation

The audit team confirms that the audit has covered the audit criteria and objectives as indicated on page 1 of this report and the verification of the

- Effectiveness of the quality management system in meeting its specified quality objectives
- Capability of the quality management system in ensuring compliance with relevant statutory, regulatory, and contractual requirements (as applicable)
- Effectiveness of the quality management system in ensuring that agreed requirements for products and/or services are met
- Effectiveness of the company's internal audit program in identifying and correcting noncompliance's with the standard and internal documentation
- Proper promotional use of certifications (certificates and certification marks). This includes checking website content and any referenced links and attachments. Use of certification mark and references in documents, product labeling and websites must not be misleading.

Based on the objective evidence, the audit team confirms that the audit objectives have been met (if applicable, with the limitations described in sections 2.6 and 2.7). The Audit Team concludes that the company's quality management system

- ☐ Conforms with the audit criteria as specified above.
- ☒ Does not fully conform with the audit criteria as specified above. The audit team identified nonconformities. Refer to findings list for more details including follow-up actions.
 - ☒ Submission of necessary documents. For details refer to audit findings list, section "Client Responses: Deadlines and Required Actions"
 - ☐ Special audit needed for verification of corrective and preventive action implementation
- ☒ Re-Certification Audit: The audit results from the last three years were considered for both the Audit planning and the current conclusion for this recertification

The Audit Team recommends

- ☐ Issuance/update/continuation of certificates
- ☒ Issuance/update/continuation of certificates upon successful closure of follow-up actions
- ☐ Suspension of certificate
- ☐ Withdrawal of certificate
- ☐ Reduction of certificate scope
- ☐ Increase of Audit frequency to semiannual surveillance

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The proposed scope statement for issuance of new or revised certificate(s) is displayed below.

For (DIN) EN ISO 13485:2021, EN ISO 13485:2016+A11:2021, ISO 13485:2016

OLD - 10578

“Design, Development, Manufacture and Distribution of Diagnostic and Therapeutic Medical Devices and Installations as well as Consulting and Services in the Field of Medical Technology. Diagnostic and Therapeutic Medical Devices and Installations: Anaesthetic Equipment, Infusion Equipment, Pediatric Equipment for Warming- and Photo-Therapy, Lung Ventilator Equipment, Monitoring Equipment, Clinical Decision Support Software, Patient Data Management Software, Equipment for Suction, Breathing-, Inhalation-, O2- and Aerosol-Therapy, Medical Gas Management and Supply Systems as well as Medical Lights”

OLD - 90464

“Manufacture and Distribution of Diagnostic and Therapeutic Medical Devices and Installations as well as Consulting and Services in the Field of Medical Technology. Diagnostic and Therapeutic Medical Devices and Installations: Anaesthetic Equipment, Infusion Equipment, Pediatric Equipment for Warming- and Photo-Therapy, Lung Ventilator Equipment, Monitoring Equipment, Clinical Decision Support Software, Patient Data Management Software, Equipment for Suction, Breathing-, Inhalation-, O2- and Aerosol-Therapy, Medical Gas Management and Supply Systems as well as Medical Lights”

NEW - 10578

“Design, Development, Manufacture and Distribution of Diagnostic and Therapeutic Medical Devices as well as Installations and Services in the Field of Medical Technology.

Diagnostic and Therapeutic Medical Devices and Installations: Anaesthetic Equipment, Infusion Equipment, Pediatric Equipment for Warming- and Photo-Therapy, Lung Ventilator Equipment, Monitoring Equipment, Clinical Decision Support Software, Patient Data Management Software, Equipment for Suction, Breathing-, Inhalation-, O2- and Aerosol-Therapy, Medical Gas Management and Supply Systems as well as Medical Lights and sterile Equipment for Medical Lights”

NEW - 90464

“Manufacture and Distribution of Diagnostic and Therapeutic Medical Devices as well as Installations and Services in the Field of Medical Technology.

Diagnostic and Therapeutic Medical Devices and Installations: Anaesthetic Equipment, Infusion Equipment, Pediatric Equipment for Warming- and Photo-Therapy, Lung Ventilator Equipment, Monitoring Equipment, Clinical Decision Support Software, Patient Data Management Software, Equipment for Suction, Breathing-, Inhalation-, O2- and Aerosol-Therapy, Medical Gas Management and Supply Systems as well as Medical Lights and sterile Equipment for Medical Lights”

ISO 9001:2015

No changes

Audit Report

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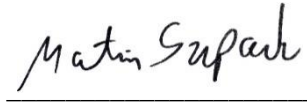
Version 1



5 Disclaimer Statement

Auditing is based on a sampling process of the available information and therefore is not a guarantee of 100% conformity with requirements. Any audit recommendations are subject to an independent review prior to a decision concerning the awarding, continuation, update, or renewal of certification. A management system certification audit (initial, surveillance or recertification audit) is not a legal compliance audit (see ISO/IEC 17021-1:2015, 9.2.1.2).

2023-10-13
Report Date


Szepannek, Martin

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6 Attachments

The Audit reporting includes this document and below referenced applicable records:

- ☐ Stage 1 Audit Report (MED_T_09.31) including relevant attachments
- ☒ Current audit finding list (MED_F_09.61), if applicable
- ☒ MHS Opening and Closing Document Package (MED_F_09.24)

7 Version History

No.	Date (yyyy-mm-dd)	Name of Author	Description of Change
1	2023-10-13	Szepannek, Martin	Completion of record
2			