1- Internal Audit information:

Activities Audited	**Design and Development Process** ISO 13485: 2016, 7.3, (21 CFR 820.30), CMDR Sections 10- 20, 32(3)(f) & 32(4)(i), 34 & 43(1)(b), Australia TG(MD)R Regs Division 3.2; TG(MD)R Sch3 P1 Cl 1.4(4), TG(MD)R Sch1 P1 2, Sch3 P1 Cl 1.4(2)&(5)(c); Essential Principles TG(MD)R Sch3 Part 1.4(5)(c)(iii)(C), TG(MD)R Sch 3 Part 1.4(5)(c)(v), MDR 2017/745, Annex XI, Part A, Annex 1 (GSPR), MDR 2017/745, Annex IX, Chapter 1, section 2.4 MDSAP Chapter 5, Tasks 1-17
Audit Date(s)	2024-06-13
Audit Date scheduled (*as per Audit schedule*)	June 10, 11, 13, 2024
Internal Auditor(s)	Gordon Forest, VL Solutions Inc.
Employees audited	Étienne Lefort, Fatima Chaouki, Tabitha Jaramillo, Lucas Posada
Department Manager	Lucas Posada

2- Audit Summary:

Design Changes:
Change procedure: SOP-15, Ver. 3.0 Technical Change Order.

SOP-15 describes the change management process including proposals, evaluations, implementation, transfer, and closure of a change.

It applies to pproduct changes including, but not limited to, design, process, software, and technical documentation changes (such as, but not limited to, specifications, and inspection protocols), and

- Quality management system documentation changes (such as procedure, templates and form, and other policies), and
- Obsolescence of documentation associated with the types of changes described above.

Changes to the product go through the TCO (Technical Change Order) process.

C2 proposed change. The process using Qualio was implemented on Feb. 22, 2024. In fact, no TCOs have been completed using the new process, but changes to C2 have been made using the Qualio process.

TCO-4 Update the WI-103028 to reference DMR programming files – Part 1: Technical Change Request. Ver. 2.0.

Anass Essenni was responsible for initiating the change.

Change description: The WI-103028 procedure needs to call for the programming files in the DMR without specifying the version number. This is because by definition the DMR contains the latest released version that needs to be used in production, and only one version is released at a time. Additionally, this will avoid updating the WI every time a new firmware file is released to just change the number of the version.

The Change request poses a series of questions which must be answered Yes, No or N/A. These were viewed on the form and indicated that only the documentation (the WI-103028) and Employee training to the current version of the WI in the DMR were required.

No.	Description	Responsible (Name)	Target Date (DD/MM/YYYY)
1	Update the WI-103028	Anass Essenni	03-04-2024
2	Production team training.	Anass Essenni	05-04-2024

Part 2 of the TCO indicate the actions taken:

New version of WI-103028 tf C2 programming procedure new version (2) was approved on 04/04/2024.

No.	Result Description	Completed By (Name)	Completed On (DD/MM/YYYY)
1	Training the production team - TRN-121	Anass Essenni	05-04-2024

I verified TRN-121, and it showed that training was given to Jefferson Da Silveria, Albert Mouawad, Ghania Chaib, Omar Dandan, and Matthew De Bruyn on 05-04-2024.

Change request for C100 using the previous system: TC) -103358 Custom Cable Supplier Inspection Protocol Update (request date: 21-11-2023).

After a number of nonconforming receptions from the supplier, additional controls were added to the supplier inspection protocols: INP-101106-SPI TremoFlo C-100 Custom Cable Assembly, and INP101106-Th TremoFlo -100 Custom made cable assembly.

Description and Justification of proposed changes (comprehensively explain all changes): Following investigations carried out through NCR-100084 and NCR-100104, it was found that there was a repeating issue with custom cables caused by the supplier during manufacturing. To reduce the occurrences of receiving faulty custom cables, the supplier inspection protocol (INP-101106-SP) will be updated to directly address the deficiencies. Changes to supplier inspection protocol includes the following:

- Check to visually inspect wires for any form of physical damage (step 30)

- Check to inspect that the crimps to not disconnect from the wires after crimping (step 31)
- Check to inspect wires and crimps such that they do not disconnect from their respective connectors following assembly (step 32)
- Continuity check across all wires of the final assembled cable (step 33)

These changes will help to reduce the occurrence of custom cables being faulty on reception. The reception inspection protocol (INP-101106-TH) was also updated to specify the AQL as per SOP-29.

Does the change directly result of action taken related to concerns arising from incidents/recalls/complaints?	Y	Change is a result SCAR-2023-002 which is a result of a result of NCR-100084 and NCR-100104. Change is also a result of NCR-100112 and NCR-100124.

If the product is a Legacy product (i.e. CE marked under MDD for distribution in EU), review the change per QP16 to assess if 'significant'.	Y	The tremoflo C-100 is a legacy product. See significant change evaluation below.

Technical Documentation affected:

Technical Document Number affected	Description	Old revision	New revision	*Implementation Code(s)
INP-101106-SP	tremoFlo C-100 Custom Cable Assembly	6	7	1
INP-101106-TH	TremoFlo C100 Custom made cable Assy	6	7	1

*Implementation Codes:

Part 6 of the TCO is the closure

After approval of the TCO, if applicable, fill out QF03-13 and attach it to the TCO to reflect the changes made. Follow QI15-01 for instructions on ERP implementation.

Applicable ☒ QF03-13 will be used to document closure of SCAR-2023-002 and communication of change to supplier. Training will be documented through Qualio.
Not Applicable ☐, Justification:

After implementation, when applicable, a review is done to validate that the implementation has successfully been made.

Certain takes need to be completed with respect to this change:

After approval of the TCO, if applicable, fill out QF03-13 and attach it to the TCO to reflect the changes made. Follow QI15-01 for instructions on ERP implementation.

Applicable ☒ QF03-13 will be used to document closure of SCAR-2023-002 and communication of change to supplier. Training will be documented through Qualio.
Not Applicable ☐, Justification:

After implementation, when applicable, a review is done to validate that the implementation has successfully been made.

101106	Communication of change to supplier	Harness is made aware of supplier inspection change	TA Wire and Harness is provided with the latest revision of INP-101106-SP rev 7	Albert Mouawad Signer ID: 3BG1GURVKE... 17 Apr 2024, 23:33:38, EDT Signing Reason: I approved this document	
	Train production	Training is documented in Qualio	Production trained on INP-101106-TH rev 7 and INP-101106-TH rev 7	Brandon Wong Ping Lun Brandon Wong Ping Lun Signer ID: ZTRRPNWNM4... 17 Apr 2024, 17:37:12, EDT Signing Reason: I approved this document	16 April, 2024
	Close SCAR-2023-002	SCAR-2023-002 is closed	SCAR-2023-002 is signed and closed	Brandon Wong Ping Lun Brandon Wong Ping Lun Signer ID: ZTRRPNWNM4... 17 Apr 2024, 17:37:12, EDT Signing Reason: I approved this document	12 April, 2024

C-100 Technical file Checklist

I verified the technical file checklist, REG-101201, Rev. 11 (May 22, 2024)

Sumary of changes made to rev. 11.

11.0	Updated Section 1 to remove full list of variants and accessories and kept reference document DES-102261 which will list all variants and accessories (TCO-5). Added Reference document REG-103402. Updated Section 2 to replace DES-102245 with REG-102204. Updated Section 3 to replace DES-102180 with REG-102204. Updated Section 7 to add REG-103099. Updated Section 8 to include device variant inspection protocols, all current work instructions, and current approved vendor list Updated Section 10 to reference the split user needs and design requirements documents and to include document titles Updated Section 11 to include latest validation for design input documents Updated Section 17 to include latest QP and SOP, removed QP1, QP12, QP19, QP20 and replaced QP15 with SOP15 Updated Section 18 to include all current effective User Manuals/IFUs, removed user manuals 101652, 102588 as per TCO-3 Updated Section 19 to include all current effective labels with label names/description Updated Section 20 to replace DES-102248 with REG-102204 Updated entire document to remove revision number of documents	As per last signature date

Section	Description	Reference	Location
0	Index of documents in the Technical File (Completed QF16-02 Technical File Checklist)	This document	Tech File TFI-102265
1	Description of the device, its function and any variants or variants that are planned	DES-102261 REG-103402	DHF 003 Technical & Design Review Records – General (8-D); DMR>Specifications Quality-Regulatory > Registrations
2	Intended use of the device	REG-102204	Tech File TFI-102265
3	Rules used for classification, class	REG-102204	Tech File TFI-102265
4	QF16-03 CE Essential Requirements Checklist (Annex I)	REG-102202	Tech File TFI-102265

Section	Description	Reference	Location
5	Risk Analysis data (using EN ISO 14971)	RSK-102166, RSK-102133	DHF 003 Risk Management Record (2-A);
6[1]	Report to Section 14 (PEMS) IEC60601-1[1] Third Edition	Refer to TFI-102265 Test data- External Electrical safety[2] report Report No. 102927294BOX-002	DHF 003 External Regulatory Tests
7	Clinical Data in accordance with Annex X of MDD 93/42 EEC, the MEDDEV 2.7.1 guidance and the NB-MED /2.7/Rec1 recommendations.	REG-102728, REG-103099	Tech File TFI-102265 DHF 004 > Regulatory Records > Australia
8	Description of the Manufacturing process including method(s) of sterilization (Annex III, clause 3; Annex VII, clause 3) and means of ensuring repeatability (Annex I, clause 10)((Annex VI, clause 3.2) only for equipment with a measuring function (e.g. Description of processes for calibration, final test, and inspection)	QP06 REV, QI06-01 INP-101336-TH – tremoFlo C-100 Device ClearFlo compatible, INP-101596-TH – tF C-100 Unit - LEMON PFT filter compatible, INP-101490-TH – tremoFlo C-100 Device Suregard compatible, INP-101772-TH – tremoFlo C-100 Unit - Vyaire Microguard II PFT Filter compatible, INP-101553-TH – tremoFlo C-100 Device DAR filter compatible, INP-101759-TH – tf C-100 Device Vitalograph – 28300. INP-101760-TH – tf C-100 Device Vitalograph – 28500, INP-102100-TH – tremoFlo C-100 Device Ganshorn compatible, INP-102078-TH – tremoflo C-100 Device – Ganshorn – SpiroDef #2 Filter WI-102163, WI-102164, WI-102167, WI-102305, WI-103208 STD-100937, STD-100938 Approved Vendor List - See Qualio	QMS> QP06 DMR> Inspection protocols DMR>Work Instructions, Device final QA/Inspection; QMS>Internal Standards; Qualio
9	Justification for the choice of material, including: Biocompatibility, Toxicological testing, (only for parts which are intended to come into contact with the patient)	DES-102214 Breathing pathway biocompatibility test reports: - Protocol 17-0048 – Final Report 2017.05.17 (VOCs) - Protocol 17-0049 – Final Report 2017.05.17 (PM2.5) - Protocol 17-0050 – Final Report 2017.05.17 (Ozone) - Protocol 17-0051– Final Report 2017.05.17 (CO & CO2)	DHF 003 Technical & Design Review Records – General (8-D) DHF 003 > Regulatory Records > VOCs Testing
10	User needs and Design Inputs	DES-102397 – TremoFlo C-100 Design Input Requirements, DES-102146 – Tremoflo C-100 User Needs	DHF 003 Design Inputs Records – General (3-A)

Section	Description	Reference	Location
		DES-101045 – TremoFlo C-100 Packaging Design Inputs DES-102122 – Electrical Accessories Design Inputs, DES-102141 – Control Unit Electronics Design Inputs DES-102239 – Software Design Input Requirements	DHF 003 Design Inputs Records – General (3-B) DHF 003 Design Inputs Records – General (3-C) DHF 003 Design Inputs Records –

11	Validation of the Design Inputs	DES-102140 tF C100 Master Validation Plan DES-100944, DES-102149, DES-101076, DES-102890 DES-102152, DES-102153, DES-102154 DES-102073, DES-102173, DES-102257, DES-102275, DES-102283, DES-102291, DES-102300, DES-102306, DES-102321, DES-102322, DES-102336, DES-102339, DES-102348, DES-102351, DES-102357, DES-102361, DES-102365, DES-102377, DES-102381, DES-102386, DES-102405, DES-102416, DES-103084, DES-103085, DES-103086, DES-103128, DES-103129, DES-103130, DES-103237, DES-103270 DES-102192, DES-102194, DES-102198, DES-102205, DES-102206 DES-102174, DES-102077, DES-102100, DES-102116, DES-102124, DES-102131, DES-102182, DES-102203, DES-102208, DES-102209, DES-102210, DES-103061, DES-103137, DES-103228, DES-103229, DES-103269, DES-103270, DES-103353, DES-103354 DES-102254, DES-102258, DES-102193, DES-102196, DES-102269 DES-100942, DES-101055, DES-102137, DES-102212	DHF 003 Design and Developing Planning Records – Master V&V Plan (1-D) DHF 003 Design Input Verifications Records – Mechanical (5-A) DHF 003 Design Input Verifications Records – Electrical (5-B) DHF 003 Design Input Verifications Records – Software (5-C) DHF 003 Design Validation Records – Current (6-A) DHF 003 V&V Test protocols& Reports and Regulatory checklists – Software (7-C) DHF 003 V&V Test protocols& Reports and Regulatory checklists – Regulatory Records and Reports (7-D)
		DES-100942, DES-101055, DES-102137, DES-102212 DES-102150, DES-102151	– Regulatory Records and Reports (7-D) DHF 003 Technical & Design Review Records - Mechanical (8-A) DHF 003 Technical & Design Review Records – Electrical (8-B)

Section	Description	Reference	Location
12	Packaging design and samples of the labeling on the packaging and on the product (Annex VII, clause 3)	101609, 101610, 101611, 101612, 101512, 101958, 101543, 101420 WI-102575 DES-10224, DES-102177	DMR > Specifications DMR > Work Instructions DHF 003 Technical & Design Review Records – Mechanical (8-A)
13	Methods of sterility, validation method and assurance	DES-102249	Tech File TFI-102265
14	List of Applicable Standards	DES-102250	Tech File TFI-102265
15	Software Development Plan	DES-102156	DHF 003 Design and Development Planning Records – Software D&D Plan (1-C)
16	Critical Parts List	Refer to TFI-102265 Test data- External Electrical safety[2] report Report No. 102927294BOX-002 Table 8.10 p.108 to 110	DHF 003 External Regulatory Tests
17	Mechanism for notification of the notified body of significant change. Copy of Post Market clinical follow up plan. (MEDDEV 2.12-2).	SOP-15, QP16	QMS
18	User Manual, Maintenance Manuals, Installation Manuals	101648, 101653, 102578, 101960, 102066, 102067, 102068	DMR>Specifications
19	Device and Accessory labels	Test Load Labels: 100987 – tremoflo C-100 Reference Load Resistance Value Label, 101799 – tremoflo C-100 Reference Load Identification Label with mfg code, 102120 – tremoflo C-100 Reference Load Identification Label, FRM-102165 – Reference Load Calibration Record Device Label: 101335 – tremoflo C-100 Airwave Oscillometry System Label Support Arm Label: 101946 – tf C100 Support Arm Label Accessory Labels:	DMR>Specifications

		101420 – Clearflo PFT Filter Bag, 101501 – Label for tremoflo software and user manual USB key, 101662 – Nose Clip bag label Packaging Labels: 101512 – ClearFlo Filter Box, 101612 – tF C-100 Shipper Box Carton only, 101945 – tf Support Arm packaging label	
20	Authorized Representative	REG-102204	Tech File TFI-102265
21	Copies of current marketing literature related to the product	tremoflo C-100 Brochure US Letter - EU English (MKT-102601-EU-EN)	Marketing
22	Declaration of Conformity (QF16-04)	REG-102247, REG-102893	Tech File TFI-102265 Quality-Regulatory – General > Registrations > Australia TGA

I verified the Declaration of Conformity: Reg 102247 is the DoC for the EU, Rev. 14 it identifies Thorasys as the manufacturer, the EU Authorized Rep. OMC NI Medical Limited (Belfast, Northern Ireland).

Hereby declare that the devices mentioned below comply with:
Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices
using the ANNEX II (excluding section 4) conformity assessment route.
EC Certificate No.: CE 607250

Product names / Produit	Model Numbers / Numéros de modèle	Class / Classe
tremoflo C-100 Airwave Oscillometry Systems: Kits		
tremoflo C-100 Kit Vitalograph – Clinical Trial Edition (28300)	101761	IIA
tremoflo C-100 Kit Vitalograph – Healthcare Edition (28500)	101762	IIA
tremoflo C-100 Airwave Oscillometry System & Accessories (kit) – Customer Specific	101773	IIA
tremoflo C-100 Airwave Oscillometry System & Accessories – UK Edition	102002	IIA
tremoflo C-100 Airwave Oscillometry System & Accessories – Europe Edition	102003	IIA
tremoflo C-100 Airwave Oscillometry System & Accessories – Lemon Europe Edition	102004	IIA
tremoflo C-100 Airwave Oscillometry System & Accessories – Switzerland Edition	102005	IIA
tremoflo C-100 Airwave Oscillometry System & Accessories – Ganshorn Edition	102110	IIA
tremoflo C-100 Kit - Ganshorn - SpiroDef Mouthpiece Variant Filter Compatible	102079	IIA
tremoflo C-100 Airwave Oscillometry System & Accessories – ERT US Edition	102585	IIA
tremoflo C-100 Airwave Oscillometry Systems: Device		
tremoflo C-100 Airwave Oscillometry System Unit - ClearFLo PFT filter compatible	101336	IIA
tremoflo C-100 Airwave Oscillometry System Unit - Lemon PFT filter compatible	101596	IIA
tremoFlo C-100 Device, Customer Specific	101772	IIA
tremoFlo C-100 Device, Ganshorn compatible	102100	IIA
tremoflo C-100 Device – Ganshorn – SpiroDef #2 Filter Compatible	102078	IIA
tf C-100 Device Vitalograph - 28300	101759	IIA
tf C-100 Device Vitalograph - 28300	101760	IIA
tremoflo C-100 Airwave Oscillometry System: Filters		
tremoflo C-100 Airwave Oscillometry System – ClearFlo F-100 PFT Filter	101421	IIA
tremoflo C-100 Airwave Oscillometry System: Software		
tremoflo C-100 software	Version 1.0	IIA
	Version 1.2	IIA
	Version 1.9	IIA
tremoflo C-100 Airwave Oscillometry System: Test Loads		
Calibrated Reference Load 2 cm H2O.s/L	100986	IIA
Calibrated Reference Load 15 cm H2O.s/L	101059	IIA
Calibrated Reference Load 5 cm H2O.s/L	101504	IIA
tF C100 Calibrated Reference Load 2cmH2O (2 years)	101798	IIA

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam

CE
2797

Notified Body performed the technical review and issued the CE certificate / Organisme notifié, a effectué la revue technique et émis le certificat CE

Revision	Description of Change	Change Reference
14.0	Added: 1. tremoflo C-100 Kit - Ganshorn - SpiroDef Mouthpiece Variant Filter Compatible [102079] 2. tremoflo C-100 Device – Ganshorn – SpiroDef #2 Filter Compatible [102078] 3. tF C100 Calibrated Reference Load 15cmH2O (2 years) [102069] 4. tremoflo C-100 carrying case [102579] 5. USB to Ethernet Adapter [102584]	TCO-103244 TCO-103310

Essential Requirements Checklist REG-102202, Rev. 12.

12.0	Updated scope to reference DES-102261 for full list of device variants, their applicable filters, their respective associated kits and accessories Updated Current User Manual References to remove French user manual 101652 as per TCO-3 and added most up to date list of current user manuals/IFUs Section 4: Updated document to include references for 15cmH_2O.s/L reference test load and 2-year variant. Section 6a: Replaced DES-102332 with REG-102728 Section 7.2: Added pFMEA RSK-103321 and risk ID P44 for defects in injection molding leading to part being too thin and resulting in minor burns. Added DES-102214. Section 8.1 and Section 9.1: Added C-100 device models 101553, 101759, 101760, 102078 and their applicable filters Section 12.6 and Section 12.7.4: Corrected ELEC reference to Electromagnetic Energy Hazard Updated references to reference current user needs and design input requirement documents (DES-102146 & DES-102397). Removed references to home use. Deleted specification of revision numbers throughout document. Updated product trademarked name from tremoFlo to tremoflo.

Product Name: tremoflo C-100 Airwave Oscillometry System
Classification: Class IIa

Scope:

Scope of this document is applicable to all device variants, their applicable filters, their respective associated kits and accessories. Refer to DES-102261 for full list.

Current User Manual References:

- 101648 tf C-100 User Manual ENGLISH
- 101653 tremoflo C-100 User Manual, US Edition
- 101960 Instructions for Use – tf C-100 Support Arm
- 102066 tremoflo User Manual – Vitalograph US Healthcare Edition
- 102067 tremoflo User Manual – Vitalograph Global (non-US) Healthcare Edition
- 102068 tremoflo User Manual – Vitalograph Clinical Trial Edition
- 102578 tf C-100 User Manual ERT Custom Edition

The checklist lists the Essential Requirement number, the description, whether it is applicable or not, Applicable standards, Thorasys Document / Procedure / Report and the Location.
For example:

Ess. Req.	Description	Appl.	Applicable Standards (ref.; version)	THORASYS Document / Procedure / Report	Location
PART I: GENERAL REQUIREMENTS:					
1.	The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of the patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. This shall include: — reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and — consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).	Y	IEC-60601-1 Ed. 3.1, EN-13485:2016 EN-14971:2019	Device design is performed according to QP03. The design requirements, which take into consideration the intended use, user, patient and environment are listed in DES-102397. As described in QP17 the risks that can affect user and patient safety are reduced as far as possible until the residual risks are deemed acceptable. Risk analysis is performed according to QP17 with the results in RSK-102133, RSK-102166, RSK-103324. Basic Safety and Essential Performance are ensured by independent compliance testing to safety standards the results of which are shown in Intertek Reports in the attachments section of the Technical File.	DHF-003/Design Records DHF-003/Risk management records

Risks must be reduced as far as possible (inherently safe design and construction).

Design Requirements for the TremoFlo are listed in DES-102397. Risk management is performed during the design process as per QP17 and the results are detailed in RSK-102133 and RSK-103324.

I verified the Risk management records: RSK-102133 (design Process), Rev. 20

Purpose: The Product FMEA provides a high-level assessment of all risks associated with the tremoflo C-100 product. Focused on the patient and user.

Project: tremoflo C-100 **DHF Number: DHF-003**
Product Name: tremoflo C-100
Maximum Residual Rating: 4A
Maximum Residual Risk Level: MEDIUM-ACCEPTABLE

Table of Contents

5 DISTRIBUTION /LIFE RISK

5.1 Transport and Storage Hazards .....

5.2 Environmental Hazards .....

5.3 Disposal and Scrapping Hazards .....

I verified the cleaning, disinfecting and Sterilization hazards;

1.8 Cleaning, Disinfecting, and Sterilization Hazards

Benefit/Risk Analysis:

By design the device breathing pathway is not intended to be cleaned, since it designed to be used with a PFT filter that ensures the safety of the patient and eliminates the risk of cross-contamination. Also, the pneumotach has been designed for intuitive dis-assembly/re-assembly in the event that it is cleaned. Therefore, the residual risks associated with measurement error and patient contamination are low and outweighed by the benefit of using the device to aid physicians in the overall medical assessment of their patients by providing patient lung function measurements.

1.9 *1.33* *1.11* *1.35* *1.37*	*Measurement error*	Device not properly cleaned due to lack or inadequate specification for validated procedures for cleaning, disinfection	Inaccurate pulmonary function assessment potentially leading to delayed treatment pending an independent and separate diagnostic evaluation in the case of an adverse pulmonary condition	3A	MEDIUM		By design, regular cleaning of the pneumotach is not required due to the use of anti-bacterial/viral filter. Measurement accuracy must be verified on a daily basis via a mandatory test load calibration procedure. By design the device is easy to clean and instruction for cleaning are simple enough and well detailed to be performed by a lay operator. The cleaning procedure is clearly described in the User	U
Usability		User Manual section 4.3 Calibration and 6.2 Cleaning.		3E	LOW	Acceptable		The likelihood that there is a measurement error due to an inappropriate cleaning specification is frequent P1=1/10. The likelihood this measurement error leads to a delayed treatment is frequent P2= 1/50. P1 x P2 = 1/500	

3- Non-Conformities:

- **NC#ID:** NCxx
- **Category:** Minor ☐ Medium ☐ Major ☐
- **NC Description** (including reference and evidence):

No non-conformities were detected for this process.

4- Opportunities For Improvement:

No opportunities for improvement were detected in this process.

Documented /Approved by	Name:	Signature:	Date:
Department Manager	Lucas Posada Signer ID: VURHTIJKP1... 11 Jul 2024, 15:51:33, EDT Signing Reason: I approved this document		11-Jul-2024 EDT
Quality Assurance	Tabitha Jaramillo Signer ID: INFXWXQWVX... 25 Jul 2024, 13:33:23, EDT Signing Reason: I approved this document		25-Jul-2024 EDT

Signature Certificate

Envelope Ref:ae760810abfcc5823fe393328b35ea5440733f21

Author:	Fatima Chaouki	Creation Date:	10 Jul 2024, 10:16:07, EDT	Completion Date:	25 Jul 2024, 13:33:23, EDT

Document Details:

Name: Internal Audit Report Design and Development Process - June 2024

Type:

Document Ref: 00d44092572e1fb9fb07cdf5ba25d88e0d6699e1cd1809f8b301e7a7fe7b36b7

Document Total Pages: 11

Name: Internal Audit Report Marketing Authorization - June 2024

Type:

Document Ref: 35eb680dbd1a9232d0e91a198247763e268c61b1c634d9ec53b5fb604075316e

Document Total Pages: 7

Name: Internal Audit Report Measurement Analysis and Improvement - June 2024

Type:

Document Ref: e4f0153e6e3c3983e69298f095766af5a9edc0186eb98890e26a801d6182ef54

Document Total Pages: 24

Name: Internal Audit Report Medical Device Adverse Events and Advisory Notice Reporting Process - June 2024

Type:

Document Ref: a991dc4e3d45975521036c90e3cb066ce56e374b6512a415b0681e0196aae39f

Document Total Pages: 3

Name: Internal Audit Report Production and Service Controls Process - June 2024

Type:

Document Ref: da29b0d0922bc5d491f9358586b448d4323c44c7e35008e429784ee251eb0262

Document Total Pages: 10

Name: Internal Audit Report Sales and Purchasing Process - June 2024

Type:

Document Ref: 3beba510df6a925fba7b5cc05328469b029c11dd914b9e48865470d09bb93668

Document Total Pages: 7

Name: Internal audit summary report - 2024 - Corrected

Type:

Document Ref: 65a58bb305e79723c1455ccd94b23e43245f0676fa0470540254f32710f5c6d5

Document Total Pages: 2

Document Signed By:

Name: Tabitha Jaramillo
Email: tabitha.jaramillo@thorasys.com
IP: 104.221.20.56
Location: MONTREAL, QC (CA)
Date: 25 Jul 2024, 13:33:23, EDT
Consent: eSignature Consent Accepted
Security Level: Email, Account Login Password Authentication

Tabitha Jaramillo
Signer ID: INFXWXQWVX...
25 Jul 2024, 13:33:23, EDT
Signing Reason: I approved this document

Name: Etienne Lefort
Email: etienne.lefort@thorasys.com
IP: 70.53.167.187
Location: KIRKLAND, QC (CA)
Date: 25 Jul 2024, 12:16:54, EDT
Consent: eSignature Consent Accepted
Security Level: Email, Account Login Password Authentication

Etienne Lefort
Signer ID: HEBIXXRYNS...
25 Jul 2024, 12:16:54, EDT
Signing Reason: I approved this document

Name: Ghania Chaib
Email: ghania.chaib@thorasys.com
IP: 197.204.13.234
Location: ALGIERS, 16 (DZ)
Date: 25 Jul 2024, 09:27:10, EDT
Consent: eSignature Consent Accepted
Security Level: Email, Account Login Password Authentication

Ghania Chaib
Signer ID: DOT5CSV9JP...
25 Jul 2024, 09:27:10, EDT
Signing Reason: I approved this document

Name: Lucas Posada
Email: lucas.posada@thorasys.com

Lucas Posada
Signer ID: VURHTIJKP1...
11 Jul 2024, 15:51:33, EDT
Signing Reason: I approved this document

IP:	69.70.57.54
Location:	MONTREAL, QC (CA)
Date:	11 Jul 2024, 15:51:33, EDT
Consent:	eSignature Consent Accepted
Security Level:	Email, Account Login Password Authentication

Document History:

Envelope Created	Fatima Chaouki created this envelope on 10 Jul 2024, 10:16:07, EDT
Invitation Sent	Invitation sent to Lucas Posada on 10 Jul 2024, 11:22:41, EDT
Invitation Accepted	Invitation accepted by Lucas Posada on 10 Jul 2024, 12:55:04, EDT
Signed by Lucas Posada	Lucas Posada signed this Envelope on 11 Jul 2024, 15:51:33, EDT
Invitation Sent	Invitation sent to Ghania Chaib on 11 Jul 2024, 15:51:33, EDT
Invitation Accepted	Invitation accepted by Ghania Chaib on 11 Jul 2024, 15:52:23, EDT
Signed by Ghania Chaib	Ghania Chaib signed this Envelope on 25 Jul 2024, 09:27:10, EDT
Invitation Sent	Invitation sent to Etienne Lefort on 25 Jul 2024, 09:27:10, EDT
Invitation Accepted	Invitation accepted by Etienne Lefort on 25 Jul 2024, 12:08:41, EDT
Signed by Etienne Lefort	Etienne Lefort signed this Envelope on 25 Jul 2024, 12:16:54, EDT
Invitation Sent	Invitation sent to Tabitha Jaramillo on 25 Jul 2024, 12:16:54, EDT
Invitation Accepted	Invitation accepted by Tabitha Jaramillo on 25 Jul 2024, 13:32:31, EDT
Signed by Tabitha Jaramillo	Tabitha Jaramillo signed this Envelope on 25 Jul 2024, 13:33:23, EDT
Executed	Document(s) successfully executed on 25 Jul 2024, 13:33:23, EDT
Signed Document(s)	Link emailed to lucas.posada@thorasys.com
Signed Document(s)	Link emailed to ghania.chaib@thorasys.com
Signed Document(s)	Link emailed to etienne.lefort@thorasys.com
Signed Document(s)	Link emailed to tabitha.jaramillo@thorasys.com
Signed Document(s)	Link emailed to fatima.chaouki@thorasys.com