Quality System Work Instruction
Mandatory Roles for Document Creation, Review and Approval

PHILIPS

1 Purpose

This purpose of this instruction is to identify the mandatory roles for creation, review and approval of the various types of documents required by the QMS.

2 Scope

This instruction applies only to those Tier 6 documents (Quality Records) that are specified in this work instruction.

3 Responsibilities

QMS Role	Responsibilities
All Employees	Author, review and approve QMS records according to this work instruction

4 Definitions and Acronyms

4.1 Definitions

Term	Definition
First In Line Manager	First in line manager is the first manager up in line that has the operational responsibility associated with the QMS role of the author. For example documents created by someone assuming the Supplier Quality Engineer role shall be signed by the Q&R manager. If that same person is also assigned in the role of project manager a different first in line manager applies.
Peer	A person with the same QMS role as the author.
Record	Document that memorializes and provides objective evidence of activities performed, events occurred, results achieved, or statements made. Records are created / received by an organization in routine transaction of its business or in pursuance of its legal obligations. A record may consist of two or more

Term	Definition
	documents
Tier 6 documents	Quality Records

4.2 Acronyms

Short	Long
BIU	Business Innovation Unit
CE	Conformité Européenne
CMWL	Configuration Management Work List
DICOM	Digital Imaging and Communications in Medicine
DoC	Declaration of Conformity
eDMS	Electronic Data Management System
HL7	Health Level Seven
IHE	Integrating the Healthcare Enterprise
IT	Information Technology
MDD	Medical Devices Directive
MDS	Medical Device Security
N/A	Not applicable
NOR-D	Notification On Release for Delivery
PDLM	Product Development Lifecycle and Maintenance
QMS	Quality Management System
Q&R	Quality and Regulatory
R&D	Research and Development
UDI	Unique Device Identifier
USA	United States of America

5 Documents

In general, documents have a single Author, can have multiple Reviewers but one reviewer per identified role, and have a single Approver if applicable.

Non-English user documentation documents are not reviewed. If approval is obtained, approved English version and translated certificate may be referenced.

Where commentators are added to the table below, they are not mandatory reviewers.

5.1 Product Development related documents

Document Type	Author	Reviewer(s)	Approver	Remark
1900 Sheet	System Engineer	– Peer – Purchasing Manager, in case content is to be agreed with supplier	First In Line Manager	N/A
Application Training Material	Clinical Application Specialist	– Approbation Officer – Application Trainer*	First In Line Manager	(*) Only if Application Training Material is prepared under responsibility of the BIU.
Australian Essential Principles Checklist	Quality Officer	– Approbation Officer – Project Manager – First In Line Manager	First in Line Manager	N/A
Canadian Change Assessment	Approbation Officer	Peer	First in Line Manager	N/A
Canadian Medical Device License (MDL) – amendment – application	Approbation Officer	Peer	First In Line Manager	N/A
CanMDR (Canadian Medical Device Regulations) requirements Checklist	Quality Officer	– Approbation Officer – Project Manager – First In Line Manager	First in Line Manager	N/A
C-BOM (Commercial - Bill Of Material) PRF (Product Representation Framework)	Product Configuration Engineer	– Product Manager – Quality Officer	First In Line Manager	N/A
CE Technical Dossier	Quality Officer or Approbation Officer	– Approbation Officer (if Quality Officer is author);	First In Line Manager	N/A

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Document Type	Author	Reviewer(s)	Approver	Remark
		– Quality Officer (if Approbation Officer is author) – Project Manager		
Clinical Evaluation – Plan – Report	Clinical Application Specialist	– Safety Manager – Quality Officer – Peer	First In Line Manager	N/A
CMWL (Configuration Management Work List)	Project Manager	Quality Officer	First in Line Manager	Review is performed as part of Compliance Status Report preparation. Approval is required at Project Closure.
Compatibility Matrix	System Engineer	– Verification Manager – Product Support Engineer	First in Line Manager	Copy holder: Quality Officer shall be informed after approval.
Configuration management plan	Project Manager	– Software Architect – Quality Officer	Program Manager	Configuration management plan may be captured in the Product Release plan or the Development Increment Plan template as well. In such cases, reviewers and approvers of the applicable document shall be used.
Conformance Statement: – DICOM – HL7	Interoperability Engineer*	– Software Architect – Product Manager	First In Line Manager*	Deliverable of other QMS. *Role outside the BIU.
CP (Compliance Plan)	Quality Officer	– Project Core Team	First In Line Manager	N/A
CSPP (Customer Services Product Plan)	Product Support Engineer	– Peer – Representative of the Market Group service organization*	First In Line Manager	*Role outside the BIU
CSR (Compliance Status Report) or Quality Status report	Quality Officer	– Project Manager – First In Line Manager	First In Line Manager	N/A
Customer Service Documentation	Product Support Engineer, or Technical Writer	– Approbation Officer* – Peer – Product Support Engineer (if Author is Technical Writer)	First In Line Manager	Commentator(s): – Clinical Marketing – Product Management – Learning Specialist – Service Representative

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Document Type	Author	Reviewer(s)	Approver	Remark
				– Operations Representative *Approbation Officer review required only for customer facing documents. For Service pack, Installation Manual may be authored by Software Engineer.
Data Search Report	Clinical Application Specialist	– Safety Manager – Quality Officer – Peer	First In Line Manager	N/A
Declaration of Conformity – European (CE) – Australian	Approbation Officer	First In Line Manager	First In Line Manager	Note: This document will be reviewed and signed outside the eDMS tool. The signed DoC will then be published in the eDMS tool without an additional workflow review and authorization.
Delivery Notes (Customer Release Notes)	Product Support Engineer, or Technical Writer	– Peer – Product Manager – Product Support Engineer (if Author is Technical Writer) – Approbation Officer	First In Line Manager	Commentator(s): – Clinical Marketing – Learning Specialist – Service Representative – Operations Representative
Deployment Verification – plan – report	Product Support Engineer	– Peer – Project Manager – Quality Officer	First In Line Manager	N/A
Design Review Report	Software Architect, Or Verification Manager, Or Product Owner (depending on type of design review)	All Design Reviewers	– Independent reviewer – Project manager – Quality Officer	N/A
Design Validation – Plan – Report	Product owner OR Verification manager	– Quality Officer – Usability Architect – Clinical Application Specialist – Product Support Engineer – Product owner OR	Project Manager	When Product owner or Verification manager author the Validation plan, the other individual shall review the documents.

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Document Type	Author	Reviewer(s)	Approver	Remark
		Verification manager (See remarks column)		
Design Verification – Plan – Report	Verification Manager	– Software Architect – Quality Officer – Usability Architect	Project Manager	N/A
Development Increment Plan	Release Train Engineer	– Project Core Team – Product owner(s)	– Program Manager – Product Manager	Development Increment Plan should be reviewed and approved shortly after Release Planning.
Development Increment Report	Release Train Engineer	– Product Owner(s) – MT representative	– Program Manager – Product Manager – MT representative	Development Increment Report should be reviewed and approved at the end of the development Increment.
Device History Record (DHR)	Quality Officer	Peer Quality Officer	Quality & Regulatory Manager	N/A
DICOM Validation Test Report	Interoperability Engineer*	– Software Architect – Verification Manager	First In Line Manager*	Deliverable of other QMS. *Role outside the BIU.
Engineering Change Request	*The author role depends on the originator**	Not applicable	Supply Chain Control Board (SCCB) chairman	*Originator can be anyone working within the scope of the QMS
Essential Requirements Checklist of the MDD (Medical Device Directive)	Quality Officer	– Approbation Officer – Project Manager – First In Line Manager	First in Line Manager	N/A
Feasibility Report	*The author role depends on the topic that is reported*	Peer	First In Line Manager	N/A
FMEA	Software Engineering	– Software Architect (Scrum) – Test Architect	Software Architect (Product)	Optional Deliverable, if applicable
ICQA (Intra Company Quality Agreement)	Program Manager	– Q&R Manager *Depending on topic, e.g.:* – Department Manager Finance – Manager Operations	Depending on scope of the ICQA the General Manager or appropriate representative of the management team	N/A
IHE Integration Statement	Interoperability Engineer*	– Software Architect – Product Manager	First In Line Manager*	Deliverable of other QMS. *Role outside the BIU

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Document Type	Author	Reviewer(s)	Approver	Remark
– Instructions for Use (English) – Quick Reference Guide	Technical Writer	– Clinical Application Specialist – Product Manager – Approbation Officer	First In Line Manager	Commentator(s): – Clinical Marketing – Learning Specialist – Service Representative – Operations Representative
Labelling requirements specification	– Requirements Analyst OR – Quality Officer	– Requirements Analyst – Product Owner – Approbation Officer – Verification Manager – Quality Officer	First In Line Manager	Labelling specification also covers the Labelling plan. Requirements Analyst and Quality officer can either be author or reviewer, but not both and cannot review their own work.
Legacy Software Assessment – plan – report	Project Manager Or Program manager	– Quality Officer – Peer	First In Line Manager	N/A
Level of Concern	Approbation Officer	– Software Architect – First In Line Manager	Approbation Officer	N/A
License Specification	Product Manager	– Product Configuration Engineer – Software Architect *Additional reviewers required:* – Purchasing Manager, if third-party licensing is included in this document	First In Line Manager	N/A
Global Launch Plan	Product Manager	– Launch Team – Approbation Officer – Peer	First In Line Manager	N/A
Marketing communication material	Product Manager	– Clinical Application Specialist – Product Manager – Approbation Officer – Legal representative*	First In Line Manager	*Role outside the BIU
Market Readiness Report	Product Manager	– Launch Team – Approbation Officer – Peer	First In Line Manager, Marketing manager of market	N/A

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Document Type	Author	Reviewer(s)	Approver	Remark
MDS2	Software Architect	Peer	First In Line Manager	N/A
Milestone Review Report	Project Manager / Program manager *	Quality officer	Project Manager / Program manager *	* - Depending on who is identified as the Project Core Team Lead for the release. In case project / program manager is the author, he can approve the report as well.
NOR-D	Quality Officer	Peer	Quality & Regulatory manager General Manager*	*General Manager is to approve only for non-conformance product release
Performance Evaluation - Plan - Report	Clinical Application Specialist	– Safety Manager – Quality Officer – Peer	First In Line Manager	N/A
Post Market Surveillance plan	Product Manager	– Safety manager – Clinical Application Specialist	First In Line Manager	N/A
Pre-installation / build instructions	Role outside the organization	– System engineer – Product Support Engineer	Role outside the organization	N/A
Pre-Market Notification – Decision	Approbation Officer	– Product Manager – First In Line Manager	Approbation Officer	N/A
Pre-Market Notification – Submission	Approbation Officer	– Product Manager – Subject Matter Experts	First In Line Manager	N/A
Product & Services Security Policy Exception Request	Software Architect	Not applicable	Product & Services Security Office (PSSO)	N/A
Product Defect Status Report	Project Manager / Release Train Engineer	All Defect Management Board Members	– Quality and Regulatory Manager – Head R&D*	*Not a QMS role
Product Deliverables Specification	Project Manager	– Product Manager – Clinical Application Specialist – Technical Writer – Product Support Engineer – Product Configuration Engineer	First In Line Manager	N/A
Product Regulatory Plan	Approbation Officer	– Peer – Product Manager	First In Line Manager	N/A

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Document Type	Author	Reviewer(s)	Approver	Remark
		– Project Manager – Quality Officer		
Product Release Plan	Project Manager	– Program Manager – Project Core Team including Supplier Quality Engineer	Program Manager	Sub-project Plans, separated from the Product release Plan, have the same Approver; however, Author, and Reviewers may be different, dependent on the specific topic.
Product Safety Risk – Management Matrix – Assessment Report – Management Report	Software Architect	– Clinical Application Specialist – Product Support Engineer – Safety Manager – Product Owner – Quality Officer – Usability Architect	First In Line Manager	N/A
Product Safety Risk Benefit Analysis	Software Architect	– Clinical Application Specialist – Product Support Engineer – Safety Manager – Product Owner – Quality Officer – Usability Architect	Quality & Regulatory Manager	N/A
Product Safety Risk Management Plan	Project Manager	– Software Architect – Clinical Application Specialist – Product Support Engineer – Safety Manager – Product Owner – Quality Officer – Usability Architect	First In Line Manager	N/A
Product Safety Risk Management Surveillance Report	Safety Manager	– Clinical Application Specialist – Software Architect	First In Line Manager	N/A
Product Security Risk	Software Architect	– Software Architect	First in Line Manager	N/A

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Document Type	Author	Reviewer(s)	Approver	Remark
- Assessment Minutes - Management Matrix		– Product Support Engineer – System Engineer – Product Security Officer – Quality Officer		
Product Security Risk Acceptance Analysis	Software Architect	– Software Architect – Product Support Engineer – System Engineer – Product Security Officer – Quality Officer	Pre-release: General Manager Post release: Product Security Officer	N/A
Product Security Risk Management Plan	Project Manager	– Software Architect – Product Support Engineer – System Engineer – Product Security Officer – Quality Officer	First in Line Manager	N/A
Product Security Risk Maintenance -Plan -Report	Product Support Engineer	– Software Architect – Product Security Officer – Quality Officer	First in Line Manager	N/A
Product Security Risk Event Report	Software Architect	– Software architect – Safety Manager – Complaint investigator – Product Security Officer – Privacy Officer	General Manager	N/A
Project Action And Decision History File	Project Manager	Not applicable	Not applicable	Baseline at iteration and milestone boundaries. No review and approval required.
Project Charter (for New Product Development)	Program Manager	See *	Member of Portfolio Management Team	* No formal review via eDMS required. Review of the Project Charter by Portfolio Management Team and Program Team shall be captured in meeting minutes. These shall be stored in the eDMS.
Project Level Agreement	Project Manager	– Q&R Manager – For involved parties:	Program Manager	Representatives from involved parties shall approve.

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Document Type	Author	Reviewer(s)	Approver	Remark
		Project Manager(s)		
PRS (Product Requirements Specification)	Requirements Analyst	– Product Owner – Clinical Application Specialist – Product Support Engineer – Software Engineer – Approbation Officer – Verification Manager – Usability Architect *Additional Reviewers required:* – Technical Writer, if warnings shall be added to the Instructions for Use – System Engineer, if the product contains hardware – Quality Officer	First In Line Manager	Mandatory roles for review are only required for the formal review and authorization at milestones. During iterative review, reviewers areselected based on the impacted requirements. For example, regulatory roles shall review only if regulatory requirements are impacted. A justification for why only identified reviewers are applicable shall be captured in the Document Change Summary Verification Manager or his delegate will ensure the accuracy of the URS to PRS traceability. Note: Additional reviewers may be involved as needed based on the impacted requirements.
Launch Decision document for Release for Acquisition	Product Manager	Launch team	Marketing Manager Approbation Officer	N/A
Release for External Software Evaluation	Clinical Application Specialist	Not applicable	Clinical Application Specialist* Software Architect* Quality Officer OR Approbation Officer*	* Approval means that delivery of Works in Progress (WIP) is allowed.
Release Notes (Technical)	Product Support Engineer, or Technical Writer	– Peer – Product Support Engineer (if Author is Technical Writer)	First In Line Manager	N/A
SDS (System Design Specification)	Software Architect	– Peer – Usability Architect Additional reviewers:	First In Line Manager	Mandatory roles for review are only required for the formal review and authorization at milestones. Additional reviewers are involved when

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Document Type	Author	Reviewer(s)	Approver	Remark
		– Product support engineer		the content change impacts that stake holder.
Security Status Form	Software Architect	– Peer – Product Security Officer	First In Line Manager	N/A
Service Support Strategy Summary	Product Support Engineer	Peer	First In Line Manager	N/A
Service Training Material	Product Support Engineer	– Peer – Technical Trainer*	First In Line Manager	* Role outside of the QMS
Site Selection Form	Clinical Application Specialist	Not applicable	Not applicable	Base lined during preparation for external Product Validation. No review and approval required.
Software deployment manual	Product Support Engineer, or Technical Writer	– Peer – Product Support Engineer (if Author is Technical Writer)	First In Line Manager	Commentator(s): – Clinical Marketing – Product Management – Learning Specialist – Service Representative – Operations Representative
Software License	Product Configuration Engineer	Product Support Engineer	First In Line Manager	N/A
Level Release /Service Pack Plan and Report	Project Manager	– Quality Officer – Approbation officer	Development Manager	Copy holder: Department Manager shall be informed after approval.
State of the Art	Clinical Application Specialist	– Safety Manager – Quality Officer – Peer	First In Line Manager	N/A
Technical Evaluation Report (TER)	System Engineer	– Peer – Quality Officer	First In Line Manager	N/A
Technology Change Assessment report	Product Manager	– Approbation Officer – Clinical Application Specialist – Usability Architect	First In Line Manager	N/A
Test Script Validation Report	Verification Engineer	– Software Engineer – Peer	Verification Manager	N/A

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Document Type	Author	Reviewer(s)	Approver	Remark
		– Verification Manager		
Third party items assessment checklist	Software Architect	– Quality Officer – Peer – Project manager – Security Officer – Supply Quality Engineer	First In Line Manager	N/A
Traceability Matrix - Validation	Clinical Application Specialist OR Product Support Engineer	– Quality Officer – Verification Manager/Product Owner	Verification Manager/Product Owner	N/A
Traceability Matrix - Verification	Verification Engineer OR Verification Manager	– Quality Officer – Product owner – * Verification Manager	First in Line Manager	(*) If Verification Engineer is the author.
UDI Device Identifier Issuance Decision	Approbation Officer	First In Line Manager	Approbation Officer	N/A
UDI Master Record	Approbation Officer	– Quality Officer – First In Line Manager	Approbation Officer	N/A
URS (User Requirements Specification)	Product Manager	– Product Owner – Clinical Application Specialist – Product Support Engineer – Requirements Analyst – Approbation Officer – Usability Architect – Quality Officer *Additional Reviewers required:* – Purchase Representative, if components are purchased – System Engineer, if the product contains hardware	First In Line Manager	N/A
User Interaction Design	Software Engineer	– Software Architect	First In Line Manager	N/A

Document Type	Author	Reviewer(s)	Approver	Remark
		– Usability Architect		
VA (Veterans Affairs) 6550 form	Software Architect	Peer	First In Line Manager	N/A
Validation Protocol	Depending on the topic this will be a: – Clinical Application Specialist – Product Support Engineer	– Product Owner/Verification Manager – Quality Officer *Depending on topics of the report, the following roles can be relevant:* – Clinical Application Specialist (Peer) – Product Support Engineer (Peer) – Usability Architect	Product Owner/Verification Manager	N/A
Verification Record Third Party Medical Device	Quality Officer OR Approbation Officer	Peer	First In Line Manager	N/A
Verification Record(s) Translated User Documentation	Not applicable	Not applicable	Not applicable	Record; External document
Verification Test Specifications	Verification Engineer	– Peer – Software Engineer	Verification Manager	N/A
Verification Test Results	Verification Engineer	– Peer *Additional reviewer to review label verification:* Approbation Officer	Verification Manager	The scope of review by Approbation officer is limited only to the test results pertaining to label verification.

5.2 Tool Development related documents

Document Type	Author	Reviewer(s)	Approver	Remark

Document Type	Author	Reviewer(s)	Approver	Remark
Design and Decision Document (including Requirements)	Software Architect	– Software Engineer – Verification Engineer – Quality Officer	- First In Line Manager - Product Manager for Tool Development *	A Tool Development Team member can be designated by the Software Architect to create the document, but the Software Architect stays responsible. * The Product Manager for Tool Development is accountable that the requirements defined reflect the Tool Request / Request for Change.
Development Increment Plan	Scrum Master	Not applicable	Not applicable	N/A
Development Increment Report	Scrum Master	Not applicable	Not applicable	N/A
Test Results Summary	Verification Engineer	– Product Owner – Software Architect	Product Owner	N/A
User manual	Software Architect	– Software Engineer – Verification Engineer – Product Owner – Tool user representatives*	First In Line Manager	A Tool Development Team member can be designated by the Software Architect to create the document, but the Software Architect stays responsible as author. * Role outside our QMS
Validation specification and report	Product Owner	– Tool user representatives* – Verification engineer	Not applicable as it is a checklist for creating validation records	* Role outside our QMS
Service Tools Release Form	Product Owner	– Software Engineer – Verification Engineer – Scrum Master	-Release Manager -Quality Officer	Copy holder: Product Support Engineering shall be informed after approval.

5.3 Compute Environment related documentation

Document Type	Author	Reviewer(s)	Approver	Remark
Compute Environment Change / Risk Analysis Form	System Architect	– System Engineer – Verification Engineer – Quality Officer Additional Reviewer(s) – Software Engineer, if changes have impact to	First in Line Manager	The identified responsibilities relate to both the Anticipated Change / Risk analysis as the Final Change / Risk Analysis

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Document Type	Author	Reviewer(s)	Approver	Remark
		application. – Purchase Representative, if changes impact hardware/software inventory. Product Support Engineer, if changes impact product supportability.		
Compute Environment to Application Compatibility Matrix	System Engineer	– Program Manager – Software Engineer Verification Engineer	First In Line Manager	Copy holder: Quality Officer shall be informed after approval.
Compute Environment Information Transfer List	System Engineer	Product Support Engineer	First In Line Manager	N/A
Compute Environment Project Plan	Project Manager	– Program Manager – System Engineer – Verification Engineer – Product Support Engineer – Quality Officer Additional Reviewer(s) Purchasing Representative, if changes impact hardware builds.	Program Manager	N/A
Compute Environment Release / Update Sheet	Project Manager	Quality Officer	Q&R Manager	N/A
Compute Environment Requirements	System Engineer	– Peer – Verification Engineer System Architect	First in Line Manager	N/A
Compute Environment Test Addendum	Verification Engineer	– Project Manager – System Engineer Quality Officer	First in Line Manager	N/A
Compute Environment Trace / Test Form – Plan Results Summary Report	Verification Engineer	– Project Manager – System Engineer Quality Officer	First in Line Manager	N/A
Compute Environment Internal Release notes	System Engineer	– Product Support Engineer Verification Engineer	First in Line Manager	N/A

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Document Type	Author	Reviewer(s)	Approver	Remark
Compute Environment Solution Documentation	System Engineer	– Verification Engineer – Product Support Engineer Quality Officer	First in Line Manager	N/A

6 Control of Referenced Documents

Documents that are referenced in a Report may contain information that underpins information in the Report. These documents typically provide data or rationales on which information, decisions or conclusions in the Report are based. These documents shall be controlled and approved in the eDMS. Approver is the First in Line Manager of the Author of the document.

7 Records

Record Name	Description
NA	NA

8 References

Reference Number	Description
0730-02-P	General Document Control

9 Document History

Revision	Description of changes
1.0	Initial version

2.0	• Tool Development related documents are added.
	• Service Innovation Engineer is renamed to Product Support Engineer.
	• Author of the CRS is the Product Manager instead of the Product Owner. The Product Owner is reviewer of the CRS.
	• Iteration plan are minutes and therefore approval is not required.
	• All documentation related to product support the Customer Service Manager shall approve. This explicitly defined instead of the First In Line manager.
	• Further explanation is given on review of SRS during iterative development and at milestones.
	• For the following documents the author, reviewers and approver are identified:
	  ○ Product Revision Release Document
	  ○ Application Training Material
	  ○ Feasibility Report
	  ○ Security Status Form
	  ○ VA6550.
	• Irrelevant remark removed on review and approval to be completed before external use of the document. This is part of Document Control procedure.
	Overall Verification and Validation Summary Report is added with the same author, reviewers and approver as the related plan.

3.0	• Compute Environment related documents are added
	• Roles responsibilities for Tool Development related documents aligned with PRP approach.
	• Rename of certain templates and roles to align with (renaming in) EICI QMS
	• Technical Writer is added as optional reviewer of the SRS, in case warnings are added to the IFU
	• For the following documents the author, reviewers and approver are identified:
	  ○ Compatibility Matrix
	  ○ Deployment Verification plan / report
	  ○ Site Selection Form
	  ○ CE Technical Dossier

Revision	Description of changes
	Technical Change Assessment report.
4.0	• NPI Logistics Manager role is removed as it does not exist anymore in the EICI QMS. • Engineering Change Request is added as it is identified as a quality record in 0500-02-W1 • The definition of First In Line Manager is added to clarify what the relation to the author is • Author, reviewer and approver of Marketing communication material, Post Market Surveillance plan and report, Canadian Medical Device License, Australian Classification Declaration, Conformation Letter of the CA, Level of Concern, Release for Acquisition Decision document and Service Support Strategy Summary are identified • Project Manager is removed from the review role of Overall Verification and validation plan and summary report as he is not a reviewer but an approver of the plan • Author, reviewers and approver for the deliverables related to Product Safety Risk management are added as identified in 0336-01-P • A Software Engineer is removed as reviewer from SDS, as the review of the content is covered by a peer Software Architect • A Product Manager is removed as reviewer from the SRS, as this role is covered by the process owner review • Document 'requirements' is removed from Tool Development related documents as the document is combined with Design and Decision Document Administrative changes: Product Configuration manager is corrected to Product Configuration Engineer
5.0	Work instruction extended with UDI. Added to section 3.1: • UDI Device Identifier Issuance Decision. UDI Master Record.
6.0	• Added N/A to Remark cells which have no remarks. • Updated the reviewer and approval for the following document types to reflect current requirement: CanMDR requirements Checklist, Classification Declaration, Declaration of Conformity, Essential Requirements Checklist of the MDD, Level of Concern, Pre-Market Notification Decision and Submission, UDI Device Identifier Issuance Decision and Master Record (CR #199). • Added Australian Essential Principles. • Approbation Officer replaced with Quality Officer from the reviewer role of the Compute Environment Solution Documentation because the document is technical in nature beyond submission activities. (CR #228) • Removed Conformation Letter of the CA because the document is not created by the BU (CR #209) • Added remark for Customer Service Documentation and Declaration of Conformity. • Removed "Medical Device Classification Assessment report" because "Classification Assessment is already listed". Differentiated between Customer and Technical "Release Notes" (CR #210).
7.0	• Changed "Validation Record(s) Translated User Documentation" into "Verification Record(s) Translated User Documentation" (Change Request #246); • Removed the "Supply Chain Control Board (SCCB) members" as formal reviewers for an "Engineering Change Request" (Change Request #250); • Changed the approver for the "Product Safety Risk Benefit Analysis" from "First in Line Manager" to the "Quality & Regulatory Manager" (Change Request #256); • Added the Product Manager as mandatory reviewer for the Customer Release Notes (Change Request #262); • Included all outputs from the new Product Security Risk Management procedure

Revision	Description of changes
	(0336-02-P, revision 3.0) (Change Request #265); • Included a new row for "DDS (Device Label)", which is to be approved by the Approbation Officer (Change Request #270); • Added the role of Quality Officer as formal reviewer of the CRS (Change Request #283); Added a new row for "Device History Record (DHR)" (CAPA # 6191057).
8.0	• Updated document with current template 0730-01-T2 Rev. 2.0. • Updated author, reviewer and approver for Iteration Plan and Iteration Report (CR #354). • Included statement for non-English user documentation (CR #367) • Added Approbation Officer to Approve Release for Acquisition Decision document (CAPA #6528363). • Added Market Preparation Team, Approbation Officer, Peer to review Market introduction plan (CAPA #6528363) • Added comment for General Manager to approve NOR-D for non-conformance product release
9.0	• Reviewed and added deliverables for RI and PRC milestones that are generated as part of QMS harmonization as defined in EICI.0002886. Updated names of Author, Reviewer and Approvers as per revised QMS artifacts.
10.0	• Admin change to add Section 5.3 to revision 8.0. Section was erroneously left off when the document was updated to the current template. (Revision 9.0 changes are not reflected in revision 10.0, because revision 9.0 was authorized according to the following implementation plans: EII.0004734 and EICI.0007439). • Admin change to update Quality Records from tier 5 to tier 6 to reflect the updated QMS tiers.
11.0	• Addition of text in section 5, that commentators are not mandatory reviewers. • Addition of commentators under "Remark" column, as follows: – Software deployment manual: Clinical Marketing , Product Management, Learning Specialist , Service Representative and Operations Representative – Instructions for Use (English) and Quick Reference Guide: Clinical Marketing , Learning Specialist , Service Representative and Operations Representative – Customer Service Documentation: Clinical Marketing , Product Management, Learning Specialist , Service Representative and Operations Representative • Release Notes (Customer): Clinical Marketing , Learning Specialist , Service Representative and Operations Representative
12.0	• Included the Canadian Change Assessment; • Replaced the Approbation Plan and Device Classification Declarations with the Product Regulatory Plan; • Australian, Canadian and European requirements checklists: ○ added Approbation Officer as a reviewer; ○ changed approver role from Quality Officer to First in Line Manager; • CE Technical File: ○ added Approbation Officer as possible author; ○ added Quality Officer as possible reviewer.
13.0	• Deleted rows for DRS and DDS from Rev 9.0 • Updated information to align with the new PDLM roles for all milestones • Addition of Verification Test results document • Addition of comment to PRS, Verification Manager to verify CRS-PRS accuracy
14.0	• Changed author of License Specification from Software Architect to Product

Revision	Description of changes
	Manager and added Software Architect as a reviewer (CR#507) • Removed Project Charter (for Product revision), DDS (device label) and Release for Delivery minutes • Updated reviewers of Labelling requirements specification • Quality Officer added as an approver for Service Tools Release Form template and removed as a reviewer • Included Product Safety Risk Management Surveillance Report • Included Product Security Risk Management Surveillance Report • Updated reviewers of Software Revision and Hotfix Plan and Report • Added Verification Manager as an author of Traceability Matrix – Verification • Iteration Plan and Report renamed to Development Increment Plan and Report
15.0	Added a row for the Verification Record Third Party Medical Device (CAPA #1531)
16.0	• Added/updated below deliverables required for the PRC milestones per the QMS implementation plan defined in EICI.0019575 and EICI.0019577. ○ Added “Supplier Quality Engineer” as an additional reviewer to the Product release plan document ○ Added roles Security Officer and Supply Quality Engineer as reviewer to Third party assessment checklist ○ Added Head R&D as approver of Product Defect Status report per 0339-01-P Defect Management R8.0 ○ As per R4.0 of 0301-01-P Clinical Evaluation Procedure: ▪ Separated Clinical Evaluation Plan and Clinical Evaluation Report ▪ Added Data Search Report, Performance Evaluation Plan, Performance Evaluation Report and State of the Art ○ As per R5.0 of 0316-01-P Launch procedure: ▪ Removed Early adopter plan and report, FOK (First of Kind) report ▪ Renamed Market Introduction plan to Global Launch Plan, Market Preparation Team to Launch Team, NPI decision document to Launch Decision Document ▪ Added Market Readiness report ○ Removed Product Safety Risk Management Surveillance Plan as per Rev 4.0 of the 0336-01-P Product Safety Risk Management procedure. ○ As per Rev 4.0 of 0336-02-P Product Security Risk management procedure: ▪ Renamed Product Security Risk Benefit Analysis to Product Security Risk Acceptance Analysis; Product Security Risk Management Surveillance plan and report to Product Security Risk Maintenance Plan and Report ▪ Added Product Security Risk Event Report, Product Security Risk Assessment Minutes ▪ Removed template to be obsoleted: Product Security Assessment Report ○ Renamed Software Revision to Level release and Hotfix to Service Pack as per R2.0 of 0339-02-W1 Design Change Work instruction • FMEA clarified as an optional deliverables • Added Approbation officer as reviewer of Verification Test results when Label verification is performed • Updated names of Author, Reviewer and Approvers as per revised QMS artifacts.

10 Document Control

Process	Owner(s)

Quality System Work Instruction

Mandatory Roles for Document Creation, Review and Approval

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Process	Owner(s)
Approval	Q&R Manager
Review	Quality Officer and/OR QMS Manager
Author	Mallikarjuna C
Approval date	See eDMS
Effective date plan	According to the following implementation plans: EICI.0019575 and EICI.0019577

End of Document

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