Review & approval			
Title	**Name**	**Signature**	**Date**
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RA/QA Manager	Tabitha Jaramillo	Tabitha Jaramillo Tabitha Jaramillo Signer ID: INFXWXQWVX... 10 Apr 2024, 14:20:01, EDT Signing Reason: I approved this document	10-Apr-2024 EDT

Change History		
Revision	**Description of Change**	**Effective Date**
7.0	- Modified the design verification steps in section 7.5 to include in supporting traceability records any second level implementation evidence documentation in addition to the summary first level references (per CAP-100046) - added in section 7.3 that applicability of standards should be specifically reviewed when defining the design requirements (CAP-100047) - added in section 7.3 that design input requirements must include requirements that define and ensure the expected life of the product of the product as applicable (CAP-100045). - removed organizational interfaces in 7.1 Planning section (ISO 13485:2016 update) - added to address requirements for delivery and post-delivery in user needs section 7.2 (ISO 13485:2016 update) - added in V&V Plan in section 7.4 and 7.5 '…statistical techniques with rational for sample size as appropriate', and also in 7.4.2 test protocol/report '…and rational including statistical basis's (ISO 13485:2016 update) - added in 7.5 & 7.6 that verification/validation shall include confirmation that the design outputs meet design inputs / or that the requirements for the specified application or intended use have been met, when so connected or interfaced with other devices if applicable per the intended use (ISO 13485:2016 update). - added list of design transfer outputs, and new design transfer form QF03-13 (ISO 13485:2016 update) - added list of DHF minimum section content in 7.8 (ISO 13485:2016 update). - added definitions, process notes, and Annex 1 for alternative steps for UOUP (User Interface of Unknown Provenance) (CAP-100042)	See paper copy
8.0	Added vendor requirements in section 7.4 (development) and vendor approval in section 7.7 (Design Transfer)	See paper copy
9.0	Added: 1. QI06-05 – Process Validation to §4 Applicable Documents 2. "Software transfer activities are performed as per QP04 Software Development	10-Apr-2024 EDT

	Lifecycle and process validation activities are performed as per QI06-05 Process Validation" to §7.7 Design Transfer (CAP-100134 and CAP-100137) 3. "Additionally, inspection protocols are not required for goods from vendors suppling off-the-shelf (OTS) parts as per SOP-5 Supplier and Subcontractor Control if only the quantity of received goods is verified against the order quantity and/or a verification that the received goods are identified with the correct manufacturer's part number/model number/reference number/etc. upon reception" in §7.7 Design Transfer Updated: 1. References from QI03-01 to SOP-29 Incoming Inspection throughout 2. References from QP15 to SOP-15 Technical Change Order throughout 3. QP05 Purchasing Process to SOP-29 Incoming Inspection in §7.7 Design Transfer 4. "Inspection Protocol are not applicable to certain category of parts as described in QP05 Purchasing Processes" to "Inspection Protocols are not required for certain parts as per SOP-29 Incoming Inspection" in §7.7 Design Transfer Removed: 1. Technical Change Orders from §8 Approval (as this is now described in SOP-15 Technical Change Order) 2. QF05-06 Approved Vendor List and QP05 Purchasing Processes from §4 Applicable Documents	

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1 OBJECTIVE

The purpose of this procedure is to provide a method to plan, implement and document medical device design and development activities. This is in order to meet or exceed customer and user requirements, while minimizing potential design-related defects and conforming to quality management standards and regulatory requirements in order to ensure that product designs are safe and efficacious.

2 SCOPE

This procedure applies to the design and development of all products, from the identification of the user and product requirements through the product's general release. It includes procedural requirements for the identification of user needs and usability requirements, the determination of product specifications, and risk management and verification and validation activities. This procedure applies also to the design changes-Technical Change Orders, SOP-15, procedure from the initial release through the products' resignation.

3 CORRESPONDENCE TO STANDARDS

Standard		**Sections**
ISO 13485: 2016; EN ISO 13485: 2016	QSR 21 CFR PART 820	Refer to QP00 Quality Manual for applicable clauses of the listed standards
MDD 93/42/EEC	CMDR SOR/98-282	
ISO 14971: 2007 / EN ISO 14971: 2013 Medical devices — Application of Risk Management to Medical Devices		All
IEC 62366:2015		Medical devices – Application of usability engineering to medical devices

Table 1: Correspondence to standards

4 APPLICABLE DOCUMENTS

Number	**Name**
QF03-01	Design and Development Plan form
QF03-02	User Needs Record form
QF03-03	Design Input Verification Record form
QF03-04	Design Specification Record form
QF03-05	Design Validation Record form
QF03-07	Test Protocol and/or Test Report form
QF03-08	Inspection Protocol and Report form
QF03-09	Technical and Design Review Record form
QF03-10	Parts list form
QF03-11	Design Inputs Requirements Record form
QF03-12	Usability Specification Record form
QF03-13	Design Transfer Record
QF06-01	Lot Sheet Form
QI06-05	Process Validation
QP04	Software Development Life Cycle
SOP-15	Technical Change Order
QP16	Regulatory Process
QP17	Risk Management

Table 2: Applicable Documents

5 DEFINITIONS

Design inputs: Design input is defined as physical and performance requirements of a device that are used as the basis for a device design. Design input therefore ranges from elicited customer inputs to requirements for addressing the intended use of the device, including needs of the user and patient to at least the top level software and hardware requirements specifications that drive detailed design.

Design Inputs Requirements (DIRs): The design inputs requirements are the translation of the user needs in requirements that are measurable and verifiable, the physical and performance requirements of a device that are used as a basis for device design. These should be specified to the level necessary, including their source, to provide a consistent basis for design decisions, design verifications and design validation. In general, design inputs include those qualities or properties

that can influence the patient and/or clinician. They should address incomplete, ambiguous, technological uncertainties, or conflicting requirements, in terms of how they will be answered by design activities.

Design Output: The results of a design activity at each design stage and at the end of the total design effort. The design outputs are verified to ensure compliance with applicable design inputs requirements. The finished design output is the basis for the device master record. The total finished design output consists of the device, its packaging and labeling, and the device master record.

Design Stage: A convenient grouping of design activities for the purpose of review and documentation that are related by their place in the logical sequence of design control. Design stages include: design & development planning, design input, design, design verification, design validation, and design transfer.

Design Verification: Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled; i.e. that the design outputs meet the design inputs requirements. There must be a verification of each of the design inputs using input unique identifiers as a cross-reference. The design verification is typically done either by testing, analyses or by inspection of the design.

Design Validation: Establishing by objective evidence that device specifications conform to the user needs and intended use (A final design validation test is the last step of the design process after which clinical use can be considered). Typically, in the final design validation step, usage of the product is simulated as originally intended (i.e., tested under defined simulated operating conditions on production units verifying that the device performs as expected according to its intended use and defined user needs). The activity should include a review with product management which should be performed as early as possible in case further design iterations are required.

Design Transfer: Ensuring that the device design is correctly translated into production specifications. Successful design transfer is more than releasing the DMR to the manufacturing division. As design outputs are translated into manufacturing specifications (DMR), the project enters into the process validation cycle that will analyse, challenge, complement, and improve the DMR. As part of this cycle, the design will be validated, and if the design outputs, including the design of the manufacturing process, meet customer requirements, the design transfer closes its loop.

Design Changes: After design activities are begun and the physical design evolves into an accepted entity, subsequent changes to the device specification(s) are proposed, evaluated, reviewed, approved, and documented per all of the design control criteria. The revised specification(s) becomes the current design goal in accordance with the procedures for: design control, design change control, and document control.

DHF: Design History File – File containing or referencing the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the design control requirements.

DMR: Device Master Record –record used to reference all information (e.g. specifications, drawings, installation, maintenance, servicing procedures, software specifications, packaging, labeling, work instructions, quality assurance procedures) required for the manufacturing of a device.

FAIR: First Article Inspection Report

Formative Evaluation: User Interface Evaluation conducted with the intent to explore user interface design strengths, weaknesses and unanticipated use errors. This relates to verifying the user interface design and is performed iteratively during the design and development process.

Intended Use: The intended use defines how, by who and in which conditions the product is to be used. The intended use is part of the design inputs.

NA: Not applicable

PR: Person Responsible

Primary Operating Function: Function that involves user interaction that is related to the safety of the medical device

QA: Quality Assurance

QMS: Quality Management System

RA: Regulatory Affairs
SOP: Standard Operating Procedure
Summative Evaluation: User interface evaluation conducted at the end of the user interface development with the intent to obtain objective evidence that the user interface can be used safely. This relates to validating the safe use of the user interface.
TCO: Technical Change Order – a controlled document used to analyze, explain, document, and approve a change, and approve the initial release of specifications (DMR) and to control all DMR changes thereafter.
TBD: To Be Determined
Technical File: Compilation of design files necessary for compliance with European regulations.
Usability Engineering File: A subset of the DHF including applicable Risk Management File items that include the records and other documents that are produced as defined by the present procedure with respect to the usability engineering requirements and outputs.
User Interface of Unknown Provenance (UOUP): User Interface or part of a User Interface of a medical device previously developed for which adequate records of the usability engineering steps per this process are not available. (see Annex 1)
User Needs: These are the essence of the design inputs. They are usually defined by the marketing group (e.g. product management). Sources of user needs include, but are not limited to, customer requests, business analyses, feasibility analyses, product design overviews, regulatory, risk management and usability requirements. The user needs define what the device must be able to do, its intended use and other user specific requirements and represent the "voice of the customer".

6 RESPONSIBILITIES

The Owner of the procedure is responsible for its application and its documentary management.
The PR (or delegate noted in the design and development plan) is responsible for managing the design activities for a given product according to this procedure and the associated instructions assigned in the Design & Development Planning. It is normally the Engineering Manager or the Project Manager for the given project. A Software Developer, or any other individual with design responsibilities, can also be assigned as long as it is consistent on the basis of the design involved. The PR approval responsibilities can be transferred to another appropriate member of the development team as long as accepted by signature by the other concerned approval members (e.g. release approval documents). For complex projects the responsibilities of the PR might be shared by other members of the project. The PR is responsible for filing the relevant documentation in the DHF and DMR and circulating to the design team where applicable. The PR is also responsible for ensuring that suitable design outputs are developed to meet the design input requirements, and that these are adequately tested. The PR must also ensure that the appropriate technical expertise is included in design reviews and other activities.
Marketing - Marketing is responsible for providing customer input to the design control process, particularly to the *user needs*. In consultation with the management, marketing is the voice of the customer during design control, to ensure that the user needs accurately reflect the needs of potential users and the goals for the device, and that the resulting medical device meets those adequately.
Quality Assurance – QA shall be responsible for ensuring that design controls are correctly followed to ensure the overall quality of our resultant products and documentation packages. QA is responsible for reviewing the verification and validation plan and confirming that it is adequate. QA is responsible for ensuring that product incorporating the change is not released for use before the agreed release requirements have been satisfactorily addressed, and QA release approval has been documented.
Regulatory Affairs – RA is responsible for ensuring that the correct applicable standards are identified, that appropriate risk management reviews are held and documented, that regulatory requirements are followed throughout design

control, and that the product and documentation are compliant with the requirements of the various regulatory requirements in the markets in which the product is to be sold. RA is also responsible for the Technical File compilation.
Engineering & Software Development – Engineers and software developers are responsible for making certain that the design is technically feasible and complies with appropriate company and customer specifications and with accepted standards. Engineers and software developers are responsible for the implementation and testing of design decisions and shall ensure that manufacturing and test procedures are adequate.

7 PROCESS

The overall flow of the design control process showing the interrelationships between all the major activities prior to the initial release of a product appears in Figure 1. The design control processes are represented in a linear waterfall model for clarity. In practice, feedback paths are required between each phase of the process and previous phases, representing the iterative nature of product development. An example of the iterative nature of product development and the parallel with the traditional waterfall representation of the development process is depicted below.

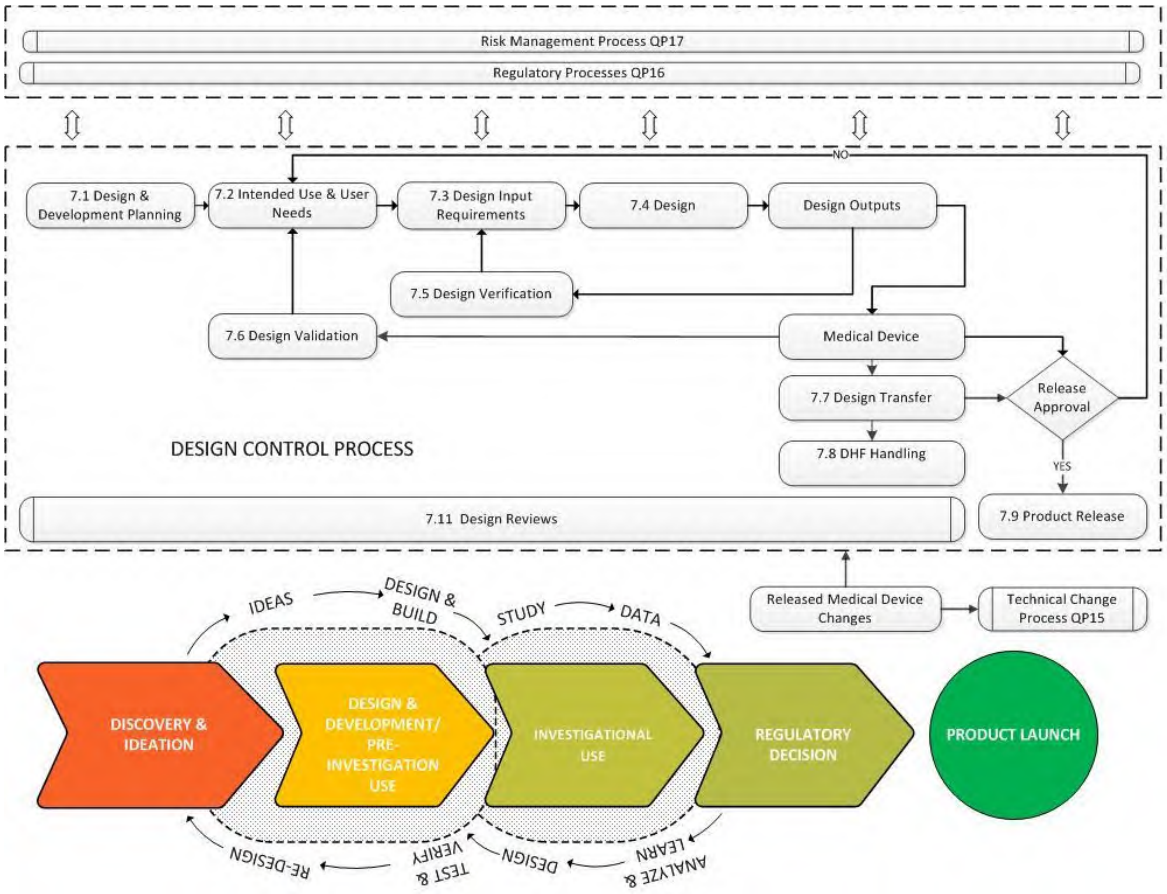

Figure 1: Waterfall model of the Design Control Process

Note: for User Interface of Unknown Provenance see Annex 1 .

7.1 Design and Development Planning

The design and development stage is the first step in the design control process. The plan must include organizational responsibilities, the major design and development activities and their scheduling. If software is a significant part of the product being designed, a software design and development plan must also be produced. The design and development planning form, QF03-01, is used to identify the design process and methodologies to be followed, planned reviews, the preliminary verification & validation plan, roles, responsibilities, authorities and all other requirements shown on the form. The risk management planning and strategy must also be defined in the design and development plan. The design and development plan may be revised, re-approved and re-issued as the design evolves in order to reflect and communicate clearly its progress

7.2 Intended Use & User Needs

The User Needs are the first layer design inputs. The intended use including the intended medical indication, the target population, the intended user profiles and the intended usage environments are defined in the Use Specification section. In consultation with engineering, marketing, distributors, consultants, or end-users, the User Needs Record form, QF03-02, is used to determine and document what the user needs are, including customer requirements, patient needs, requirements for the intended use, usability, regulatory requirements, requirements for delivery and post-delivery activities, any additional requirements as appropriate. Previous consultation and research conducted for similar or related projects may be used.

7.2.1 Usability Engineering Specification (USE SPECIFICATION)

The usability engineering specification is defined using form QF03-12 Usability Specification Record:

- Use Specification per IEC 62366-1 is partially covered by User Needs QF03-02 for the summary of the intended use including the intended medical indication, the target population, the intended user profiles, intended usage environments;
- Operating principle, primary operating functions;
- Frequent use cases and reasonably foreseeable worst-case scenario;
- Potential usability known or foreseeable hazards and hazardous situations.

The usability engineering specification serves as an input for the usability design input requirements that need to be verified and validated. The known or foreseeable hazards and hazardous situations identified in the usability engineering specification also feed into the risk management file as hazard-related use scenarios.

7.3 Design Input Requirements, Preliminary Risk Assessment and Regulatory Plan.

In simple projects, the design input requirements (DIR) may be defined in a single design input record using form QF03-11. When a more complex project is decomposed in various design items, one design input record per design item might be used to define and document the design inputs. The user needs must be reviewed for their applicability and assigned to what is to be designed. Standards should be identified and reviewed for applicability and compliance as required in the design input information. DIRs must include requirements that define and ensure the expected life of the product as applicable. Tools such as a requirement traceability matrix might be used to facilitate this process. Using the design input form, the applicable user needs are translated into quantifiable and verifiable design inputs requirements. As with other DIR types the usability DIRs are recorded on the design input requirement form QF03-11. Early in the design, the design inputs must be reviewed to ensure that they are complete, clear and non-conflicting. The preliminary risk assessment must also be reviewed early in the design process and assigned to design inputs if applicable. The Risk Management File,

the Usability Engineering File and design inputs must be updated as needed throughout the design process. The risk management file is updated as per QP17 Risk Management. Finally, the Regulatory Plan must also be elaborated early in the design process as described in QP16 Regulatory Processes.

7.3.1 Usability Design Input requirements (USER INTERFACE SPECIFICATION)

The user interface specification is a subset of the design input requirements that contains the detailed and testable requirements and shall consider the usability engineering specification, the misuse cases and the hazard-related use scenarios and are also documented in one or more design input record form. For example, part of the user interface specification may be part of the software requirement specification (SRS), the accompanying documentation design inputs, alarms design inputs etc. Examples of user interface design requirements are:

- The display shall be visible at a distance of 1m to three people standing side-by-side, with all able to read the text.
- The medical device shall be capable of producing an auditory alarm signal with a sound pressure level adjustable over the range of 45 dBA to 80dBA when measured at 1m from the front of the medical device.

The user interface specification shall also include:

- An indication as to whether the accompanying documentation is required; and
- An indication as to whether medical device-specific training is required.

Note: for User Interface of Unknown Provenance see Annex 1 .

7.4 Design

Design outputs are generated to provide necessary information for the controlled purchase, production, and supply needed to build the finished device. This includes the mechanical, electrical and software design thru final specifications and the overall product specifications including supplier requirements as well as potential supplier meeting those requirements. The design specifications constitute the design output and include but are not limited to technical drawings, hardware or software design specification documents, software architecture specifications, schematics, printed circuit board layout files etc.

The design specifications and prototypes are used as inputs to evaluate the risks and revise the risk assessment at appropriate times. As the design progresses, the required risk control measures are incorporated into the design and documented in the DHF in technical summary records or other design control documents such as detailed design specifications, engineering notebooks etc. The Verification and Validation (V&V) Plan must also be initiated during the design process. The Verification and Validation Plan can be part of the design and development plan for small projects but will typically be a stand-alone document. If practical a separate software V&V plan may also be produced. The V&V plan should be updated throughout the execution of the project in order to reflect and communicate clearly its progress. The plan should detail the scope, objective (including reason), overall criteria, statistical techniques with rational for sample size as appropriate, major assumptions, risk management considerations, test planning details, and hardware requirements. The V&V plan should both cover design verification and design validation. The compilation of these documents is the responsibility of the PR. For externally performed tests that follow standard protocols (e.g. IEC 60601), internal approval signatures are not required.

7.4.1 Suppliers for R&D

- Vendors used for R&D (includes material suppliers, preliminary product testing labs and consultants) are evaluated per QP05
- Laboratories and test houses used for V&V and product safety certification are qualified per QP05

7.4.2 User Interface design

As part of the V&V plan, a user interface evaluation plan for the user interface shall be elaborated. This plan can be part of the device master V&V plan or stand alone.

The user interface evaluation plan shall:

a) Document the objective and identify the method of any planned formative evaluations and summative evaluations
b) If usability tests are employed,
    - document the involvement of the representative intended users and user profile to which they belong
    - document the test environment and other conditions of use based on the use specification (usability engineering specification)
    - specify whether accompanying documentation is provided during the test
    - specify whether medical device-specific training is provided prior to the test

Formative evaluations are design verifications to ensure that the design is meeting the applicable requirements and going in the right direction. The formative evaluation planning shall address:

- The evaluation method being used (survey, simulated use etc.)
- Which part of the user interface is evaluated; and
- When the user interface evaluations will be performed.

The summative evaluation planning can be finalized once the formative evaluation is completed and it shall specify for each hazard-related use scenario:

- The evaluation method and a rationale that the method produces objective evidence;
- Which part of the user interface is evaluated;
- Where applicable, the criteria for determining whether the information for safety is perceivable, understandable and supports the correct use of the device;
- The availability of the accompanying documentation and provision of training during the evaluation;
- For a usability test
    - the test environment and conditions of use and a rationale for how they are representative of conditions of use; and
    - the methods of collecting data during the usability test for the subsequent analysis of observed use error.

The design of the user interface focuses on the user needs and requirements and should be conducted in an iterative manner and make use of formative evaluations to ensure requirements are met throughout the design process. The risk management file may need to be updated as new risks are identified as part of this process.
Note: for User Interface of Unknown Provenance see Annex 1 .

7.4.3 Test protocols and reports

Test protocols and reports are used throughout the design process to test the safety, efficacy and performance of items being designed and are an essential part of the design verification and validation. Test results also provide valuable risk management data and should be used where possible to measure the effectiveness of risk mitigation measures.
Test protocols should include, as applicable, the objectives, applicable standards, the methodology (equipment, sample size and rational including statistical basis, environmental conditions etc.), requirements for equipment calibration and design traceability (lots and associated design revision tested) and the acceptance criteria. Test protocols shall be approved prior to the related testing. Modifications to approved protocols and their rational are to be reviewed and approved by the original approver(s). Tests must be executed as per the test protocol and any deviations and the acceptance criteria must be documented in the test report at the time of occurrence. Test protocols and reports are documented as per form, QF03-07.

7.5 Design Verification

Design verification occurs throughout the design stage in an iterative manner and includes the formative evaluation of the user interface design and other usability design elements. The results of the design verification are summarized in the design verification record by filling the form, QF03-03. The applicable design inputs requirements, risk analysis elements are listed in the design verification record along with their corresponding design outputs for which they are verified against. The verification protocols (if applicable) and the verification reference documents used to verify each design output are also listed in the design verification record as well as the status and outcome with respect to the acceptance criteria of each verification element and the result of the risk mitigation action. If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), the verification shall include confirmation that the design outputs meet design inputs when so connected or interfaced. The verification reference documents that are cited or any supporting traceability record should also include sub-references if these contain the main verification information (for completeness and to facilitate traceability).

7.6 Design Validation

The design validation process might be broken down in various design validation steps and follow a V&V plan if needed. The details of how a design validation will be conducted must be defined in an approved validation protocol before the start of any validation process. The results of a design validation must be documented in an approved summary report after the completion of the validation. Design validation should be carried out on initial production units (or their equivalents) in actual or simulated use under defined operating conditions. The risk assessment for the device should be consulted when drafting the design validation protocol(s). Design validation must include software validation where software forms part of the device. The software might be validated through a system validation where applicable. The design validation form, QF03-05, is used to document the design validation process. If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), the validation shall include confirmation that the requirements for the specified application or intended use have been met when so connected or interfaced. The design validation record is a list of the user needs and the validation protocols and validation reports used

to validate the product against the user needs. The status and outcome with respect to the acceptance criteria of each validation element is also included in the design validation record.

The summative evaluation of the usability of the user interface consists in validating that the user interface is safe and usable. The summative evaluation is performed for the hazard-related use scenario documented in the usability engineering specification and the risk management file and done according to the user interface evaluation plan. The analyzed data from the summative evaluation shall provide objective evidence that the residual risks are acceptable as per the risk management process. If new use errors, hazardous situations or hazard-related scenarios are discovered during the data analysis these need to be considered and re-evaluated by going through the applicable steps of the design control process (section 7.2 to section 7.6) and the risk management process.

7.7 Design Transfer

The Design transfer stage ensure that design outputs are verified as suitable for manufacturing before becoming final production specifications. This stage is necessary to ensure that manufacturing controls are in place to control the quality of products in normal manufacture, through inspection and testing, or validation of production processes where appropriate. Elaboration of the inspection protocol by Engineering is described below as it is an important design transfer step to communicate the criteria for parts acceptance to Manufacturing and/or the suppliers.

Assessments will be conducted with manufacturing representatives (including supplier representatives as applicable) to review product specifications/requirements and how these will be assured in production or in sourcing. The assessments will address the following requirements and their implementation/execution/sourcing as applicable and commensurate with the associated product risks and also per the evaluation results of the supplier per QP05 (e.g. increased inspection in the case of poor conformance by supplier):

- Production/purchasing specifications
- Raw materials or subcomponents
- Inspection requirements, specifications, equipment
- Applicable processes, process capability, and required equipment
- Equipment qualifications and process validation requirements (including the justification for existing validations/qualifications)
- Gauge repeatability and reproducibility requirements
- Manufacturing/production travellers/routers
- Process work instructions
- Training Requirements
- The planning and execution of initial production samples for assessment (e.g. first article layout sample evaluation)
- The selection of supplier(s) including approval requirements per supplier management procedures.
- Ensure suppliers on the AVL

The plan and its execution results will be documented per form QF03-13 Design Transfer and will be subject to a Design Review (form QF03-09 Design Review) including the attendance/approval of any responsible parties that are additional to Design Review Board (e.g. validation responsible party). Multiple reports may be applicable to allow addressing different components and to document the evolution/progression of Design Transfer activities until the final release is completed.

Software transfer activities are performed as per QP04 Software Development Lifecycle and process validation activities are performed as per QI06-05 Process Validation.

Inspection protocols shall be generated by Engineering using QF03-08 form or using QF06-01 form within the ERP system and are to be made easily accessible for the Manufacturing Department. As a good practice, the first receiving inspection of a part should be conducted jointly by the person responsible for quality control and Engineering to ensure that QC fully understands the design, its key features as well as to confirm that the inspection protocol is appropriate to verify that the supplier has met the specifications. Engineering should also assist the person responsible for assembly in building the first units and performing final product inspection.

Inspection Protocols

An inspection protocol ensures that all outgoing products meet their specifications. Inspection done on the part or assembly shall ensure that the specifications are met on a lot inspection basis or on a serial basis mainly for complete systems.

Inspection Protocols are not required for certain parts as per SOP-29 Incoming Inspection. Additionally, inspection protocols are not required for goods from vendors suppling off-the-shelf (OTS) parts as per SOP-5 Supplier and Subcontractor Control if only the quantity of received goods is verified against the order quantity and/or a verification that the received goods are identified with the correct manufacturer's part number/model number/reference number/etc. upon reception.

It shall include the following:

- Revision of the inspection protocol to be incremented as necessary and independent of the part revision;
- Instructions on how each measurement is made and who is to make it (Manufacturing, Supplier, or a 3rd party). Unless otherwise specified, the inspection steps are performed by Thorasys;
- Critical dimensions if applicable;
- Sampling plan; whenever sampling is required due to the fact that it is impractical to process every unit of the lot to be examined, the appropriate statistical technique must be used. Determination of the adequate method must be done by Engineering and in accordance with *SOP-29 Incoming Inspection*. Unless otherwise specified, the sampling plan is 100%;
- Necessary certificates and standard verifications if applicable;
- Appropriate mating, testing and evaluation if applicable;
- Quantity to inspect if applicable;

7.8 Handling of DHF

The DHF must be stored as specified in the document control procedure. The DHF is a living document to which records will be added to as a result of a design change or additional information critical to the design becoming available.

The DHF shall be maintained including the following minimum sections to include all related documentation as defined:

- Design and Development Plan
- Design Inputs
- Risk Management File (risk records per QP17)
- Regulatory Plan (per QP16)
- Design & Risk Management Reviews

- Design Outputs
- V&V Plan
- Design Verification
- Design Validation
- Software Section (Architecture Design, Detailed Design, Unit Tests, … per software design procedure)
- Design Transfer
- DMR list – includes references to Design Output documents, and Design Changes and Release TCOs
- Additional Usability Engineering File information not included in the other DHF items

7.9 Product Release

Once the design & development planning, design input, design review, design output, design verification, design transfer, and design validation stages have been completed, the outcome of those stages, the regulatory status of the device, and the risk analysis must be reviewed before allowing product release. This review is made through the elaboration of the Technical Change Order for the release, per SOP-15 Technical Change Order.

7.10 Technical Reviews

Technical reviews are used to document relevant background, issues, options, and recommendations, and any decisions taken in a technical review meeting with regards to a technical aspect of the project. The form QF03-09 is used for technical review records.

7.11 Design Reviews

Formal design reviews must be conducted throughout the design and development of the device to evaluate the design requirements, the design's ability to meet those requirements, identify and resolve major problems, and confirm the completion of key design control activities. A design review is to review the overall needs and uses of the device and the ways in which those are met and demonstrated, and design elements that have major implications to those, not the design details discussed in a technical review described above. The technical review form, QF03-09, may also be used for the design reviews but is not required. Approval of design control documents implies that a design review was conducted. Design reviews must include representatives of all functional areas concerned with the design elements to be reviewed, an individual or individuals who do not have direct responsibility for the design elements being reviewed, as well as any specialists needed. These individuals must be part of the design control documents approvers.

Design reviews may be held at any time during the design process, as determined by the PR, or as noted in the Design & Development Plan to ensure that formal documented reviews are conducted as appropriate during the device's design development.

- **Design Inputs:** The design inputs should be reviewed in a design review meeting for approval by the appropriate participants as given in Table 3. Design inputs may be updated or changed at any time during the design process following approval through a design review and appropriate documentation with the same original approvers. Design Inputs Review Meetings should also include a review of the initial risk assessment as listed in an initial version of the Risk Management File.

- **Design:** Design reviews of the risk management file, design specifications and the V&V plan should be performed for approval at appropriate times dictated by the design progress.

- **Design Verification:** Design reviews of the design verification records should be performed a minimum of once for approval at appropriate times dictated by the design verification progress.
- **Design Validation:** Design reviews of the design validation records should be performed for approval at appropriate times dictated by the design validation progress.

The results of design review, including identification of the design, the date, and the individuals performing the review, are documented in the DHF.

7.12 Design Changes

Changes to a device that do not affect the customer requirements, patient needs, intended use, function, performance, or fundamental design do not in most instances require the use of this procedure, and should be controlled by following the Technical Change Order procedure, SOP-15 Technical Change Order.

7.13 Usability Engineering Management

The aims of the usability engineering process are to deliver easy to use and safe products in the intended context of use, and by intended users (whether by caregivers or patients themselves). Patient and User interactions with the medical device shall be considered throughout the design control process. Usability will evaluate interactions related to transport, storage, installation, operation, maintenance and repair, and disposal of the medical device. Safety to the patient and user resulting from primary operating functions, interactions during frequent used functions, frequent used case scenarios and worst use case scenarios (misuse cases) with the medical device shall be evaluated during risk assessment and appropriate risk control measures incorporated into the design. Usability requirements shall be considered in preparation of accompanying documents to the medical device, including User Manuals, Instructions for Use, technical descriptions, installation and/or maintenance instructions. As with other types of requirements, design inputs arising from usability interactions will be verified and validated with suitable acceptance criteria according to the aforementioned design control stages. The verification and validation of the usability requirements and usability user needs are done as part of the verification and validation activities.

A summary report can be prepared using the technical review form, QF03-09, to help communicate the usability / human factors activity on a project, documenting the steps taken to mitigate risk to the user. It typically includes, but is not limited to, the following details:

- intended device users, uses, environments and training
- description of the device user interface
- summary of known use problems (device under consideration and other related devices in market)
- user task selection and prioritization (based on the risk management file)
- summary of formative evaluations
- results of summative usability testing (including manual validation)
- the benefit-risk status of the device from the risk management file
- conclusions

Note: for User Interface of Unknown Provenance see Annex 1 .

7.14 Technical File Handling

The Technical File is a living document that must be updated to reflect any changes to the device. Each time a design control record or any other document/component part of the Technical File Checklist of the device (QF16-02) is created and or modified, the Technical File needs to be updated to reflect the change to the device. In addition, the Technical File must be reviewed at a minimum once a year to ensure compliance with the applicable regulations and that its content is accurate and up to date. The review of the technical file must be recorded as a revision line in the Technical File checklist of the Technical File.

8 APPROVALS

An approver is a person appointed to represent a particular functional area. The small size of the company means that in some instances several functional approvals will be approved by the same person; however, the functional approval signatures must include at least two different people. In some instances, assistance will be sought from consultants, collaborators and other professionals outside the organization, and as long as the individuals are appropriately qualified, familiar with the relevant procedures, and the subject of the documents. External personnel may be signatories for design control documents.

It is the responsibility of the PR to ensure the design control documents are approved by the appropriate individuals within the company. The following functional approvals are suggested for design control documentation:

Design Record	Person Responsible	Electrical Engineering	Software Product Manager	Software Developer	VP Operations and RA/QA	Marketing	CEO	VP R&D
Design & Development Plan	R	O	R	O	R	O	R	R
User Needs	R	O	R	R	O	R	R	R
Design Inputs-Design Inputs requirements	R	O	O	O	O	O	O	O
Design Specification	R	O	R	O	O	O	O	R
Usability Specification	R	O	R	O	O	O	O	R
Design Verification	R	O	R	O	O	NR	O	R
Design Validation	R	O	R	O	R	NR	O	R

Design Record	Person Responsible	Electrical Engineering	Software Product Manager	Software Developer	VP Operations and RA/QA	Marketing	CEO	VP R&D
Design Transfer Record	R	O	O	O	R	NR	O	O
Technical & Design Review	R	O	O	O	O	O	O	O
Test Protocol and Report	R	O	O	O	O	O	O	R
Inspection Protocol and Report	R	O	O	O	R	O	O	O

R= Required NR = Not Required O= Optional, case by case basis

Table 3: Functional approval of design control documents

9 Documentation and record control

Description	**Record conservation**		
Quality assurance document or record	*Where are they?*	*Indexation method*	*Archive duration*
DESIGN HISTORY FILE			
QF03-01 Design and Development Plan	DHF Binder: kept at the PR desk while the project is active and for up to 6 months following the general release; must be visible and accessible to others. Obsolete documents should be kept in the DHF as well. DHFs are otherwise kept in an identified protective cabinet until the product is obsolete. Thereafter DHF binders are kept in a filing cabinet or other type of container in the archive location of the company identifying the contents and the archive duration time.	By project name and number	10 years minimum
QF03-02 User Needs and Design Inputs Requirements Record			
QF03-03 Design Input Verification Record			
QF03-04 Design Specification Record			
QF03-05 Design Validation Record			
QF03-07 Test protocols and or report			
QF03-08 Inspection protocol and Report			
QF03-09 Technical and Design Review record			
QF03-10 Part List			
QF03-11 Design Input Requirements Record			
QF03-12 Usability Specification Record			
QF03-13 Design Transfer Record			
Design documents: Initial drawings, sketches, analysis, design concepts, software algorithms etc.			
Other documents if applicable			
General design documents that may be common to multiple projects/products	Common DHF Binder: Obsolete documents should be kept in the binder as well as being clearly identified. Only terminated general design documents can be archived, being kept in a filing cabinet or other type of container identifying the contents and the archive duration time.	Per type and name (e.g. OTS / Delphi)	10 years minimum
DEVICE MASTER RECORD			

DMR documents (e.g. parts lists, mechanical and electrical drawing specifications, software specifications, user manual, files configuration, labeling and packaging specifications, inserts, etc..)	DMR filing cabinet. Obsolete documents should be kept in the DMR as well being clearly identified. Only Obsolete or terminated product documents can be archived, being kept in a filing cabinet or other type of container identifying the contents and the archive duration time.	By part number and grouped by product number	10 years minimum
Electronic record controls: Not applicable – all records are printed matter.			

Table 4: Documentation and record control for the design control process.

Annex 1: Evaluation of a User Interface of Unknown Provenance

For User Interfaces of Unknown Provenance (UOUP) (or the user interface parts that are of unknown provenance) that were designed prior to the publication date of the IEC 62366:2015, February 6, 2015, and also for which adequate records per the normal procedure steps are not available, the following process step modifications are to be alternately applied. However, if any modifications are made to the User Interface or its parts, only the unchanged parts of the User Interface remain UOUP and the changed parts of the User Interface are subject to the normal steps:

a) The Use Specification per IEC-62366-1 Sect. 5.1 shall be documented per the normal process as part of the User Needs and Design Inputs Requirements Record, with, for those Use Specification items that are required per the standard but which are not included in the existing applicable User Needs and Design Inputs, these shall be additionally recorded or referenced in the usability report below.

b) Perform and summarize the review of all post-production information including complaints and field or servicing reports for incidents or near incidents, and then identify all cases of use error that could result in a hazardous situation or where field information suggests hazards or hazardous situations that could have been caused by inadequate usability. This shall be documented in a usability report in the Usability Engineering File.

c) Review and update the risk analysis for the device to take into account the hazards and hazardous situations arising out the cases noted in (b) above.

d) For all identified risks (i.e. hazards and hazardous situations) per (c) above, implement and document adequate risk controls or mitigations such that all risks are reduced to an acceptable level per the Risk Management Procedure. This includes any new risk or the modification of existing risks that stem for the new risk information or risk controls.
   If this involves any changes to any part of the User Interface, those changes shall not be considered UOUP and shall be subject to the normal process steps.

e) The device Risk Report shall be updated per the above information including the overall residual risk acceptability as required per the Risk Management Procedure.

Signature Certificate

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