APPROVAL

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PURPOSE

This procedure defines the development life-cycle of medical devices from the idea to the realization of new or changed products. It includes the relationship between the design, risk management, and usability engineering processes.

Furthermore, it defines the activities that shall be performed by ASPIVIX SA versus outsourced to specialized and approved suppliers.

SCOPE

This procedure applies equally to the development of new medical devices and to the changes made after initial product release at ASPIVIX SA including references to software life cycle sub-processes related to software development, software maintenance, risk management, software configuration management, software problem resolution and interconnections between them. This includes (but is not limited to) creation and changes of:

- design & development planning
- intended use
- product & production design
- verification and validation of new or changed design
- clinical evaluation
- process validation
- Design History File (DHF)
- Design Master Record (DMR)
- Device History Record (DHR)
- conformity assessment

Furthermore, it might cover the handling of OEM products of which ASPIVIX SA is the legal manufacturer.

RESPONSIBILITIES

Responsible for implementing and maintaining this SOP is the head of R&D (CTO).

Project Leader (PL) must respect instructions of this procedure.

DOCUMENT HISTORY

Description of Changes	Version
Initial version	A
Details about role/function/resp. in a project for Design Review and Design Development Plan + details about design transfer + add details about feasibility phase + details about flowchart	B
Add clarification design transfer process + Technical Documentation + link SOP-104 CAPA	C
Add instruction CE marking process INS-200-2	D
Replacement of T-200-17 with T-200-17A (test protocol) and T-200-17B (test report)	E

Update of the section 2.1.2, by adding the newly created templates Product Intended Use (T-200-26) and Product Description (T-200-27).	F
Update to include the rename of Hazard assessment template (T-302-3), the distinction between SOP-103 Complaints and SOP-108 Vigilance Reporting and clearly define when additional design reviews are done in section 1.2	G
Updated with references to software lifecycle procedures and include clear references to the locations of the DHF documents in section 2.6	H

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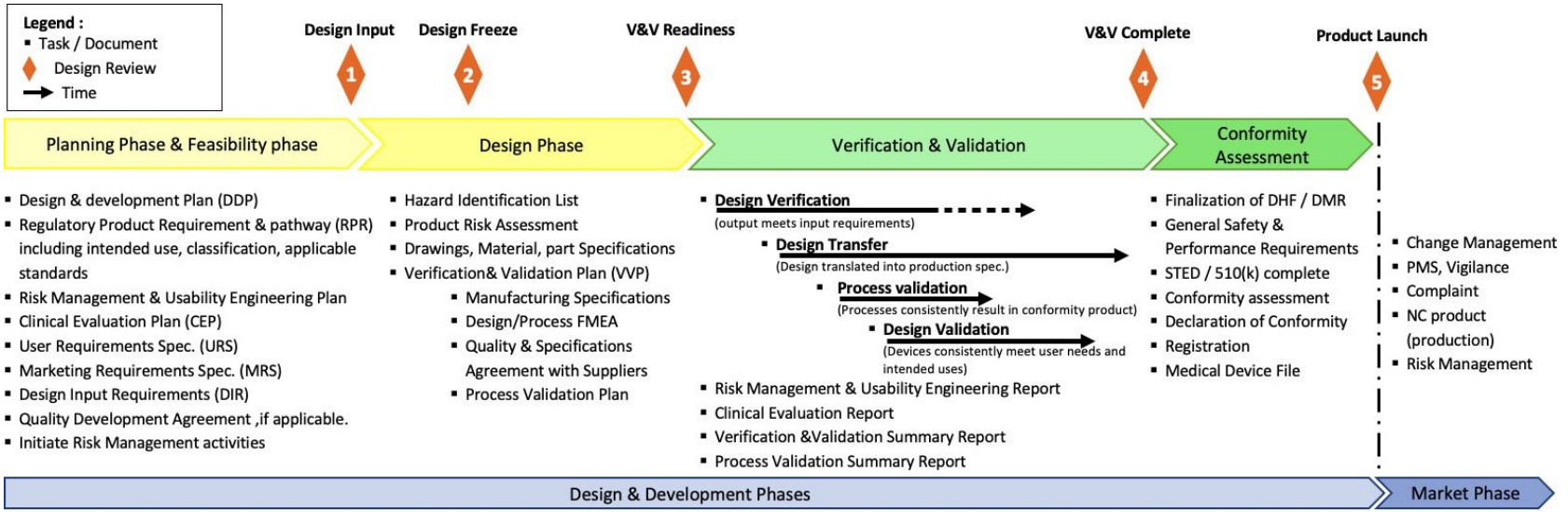
1 PROCEDURE FLOWCHART

1.1 DESIGN & DEVELOPMENT LIFE-CYCLE FLOWCHART



The design & development life cycle starts with the planning phase, which is sequentially followed by the design phase, verification and validation, conformity assessment and market and post-market phases.
The software development process (if applicable) starts in parallel with the design and development process. Applicable records are opened and populated according to SOP-208 Software development.

During the life-cycle, the status of design & development is reviewed at four critical points (Design Reviews 1, 2, 3, and 4), which are explained in the next section. In practice, different phases can overlap to enable efficient work results. However, the respective Design Reviews have to be performed sequentially.

Although certain activities may be outsourced, ASPIVIX SA will perform all reviews as defined in this procedure. Suppliers involved in the respective review topics shall be invited to participate as well.

1.2 DESIGN REVIEWS ALONG D&D LIFE-CYCLE

The review, verification and validation of each main design & development stage are defined as Design Reviews (1 to 5; see also flowchart). At these stages, the project team performs Design Reviews to clarify the current design status and to identify any potential problems as gaps to the respective requirements. The software development status is considered during main design review meetings.

The main focus per milestone is non-exhaustively listed below:

Design Review 1	Design Input (Review of design input requirements)
Design Review 2	Design Freeze (Review of drawings, material / part specifications, risk assessments, verification and validation plans, and supplier specifications & quality agreements with critical suppliers)
Design Review 3	Verification and Validation Readiness (Review of manufacturing specifications, supplier specifications & quality agreements with critical suppliers, process validation plan and V&V Plan (test specifications)
Design Review 4	Verification and Validation complete (Review of design verification, design transfer complete, process validation complete, test reports, risk management & usability engineering report, clinical evaluation report)
Design Review 5	Product launch (final review of deliverables & traceability matrix & process traceability matrix, declaration of conformity (draft; not signed))

Depending on the project, product, or complexity, additional reviews following Design Review 5 may be conducted as necessary.

Design Reviews include:

- Confirming that design inputs are complete and internally consistent;
- Reviewing design verification activities to determine whether the design output meets functional and operational requirements;
- Ensuring that the design is compatible with components and other accessories;
- Confirming that safety, reliability, service and maintenance requirements are met; and
- Determining whether labeling and other requirements are satisfied.

The review team shall consist of the representatives of all functions concerned with the design stage being reviewed (which includes representatives of critical suppliers, if applicable), at least one individual who does not have direct responsibility for the design stage being reviewed (independent reviewer), as well as any specialist(s) needed. Problems shall be identified and appropriate action defined and implemented.

Records of all Design Reviews (incl. identification of the design, method(s), the date and the individual(s) performing the review, shall be documented in the DHF based on the template T-200-4.

Note: the same template shall also be used for potential additional and technical reviews.

2 PROCEDURE DESCRIPTION

2.1 PLANNING PHASE & FEASIBILITY PHASE

2.1.1 DESIGN PLANNING

Two main activities are performed: i) Research for Product Feasibility and ii) Definition and Planning of the Design.

The research for product feasibility phase should end with the following elements:

- Proof of concept,

- Prototype,
- List of potential suppliers,
- Estimation of potential product cost.

During the research product feasibility, different plans must be set up:

- Design & Development activities shall be planned based on template **Design & Development Plan (DDP), T-200-1** and validated by the CEO**.** In this template, important topics like scope, team, timelines, quality assurance, intellectual property, market, reimbursement strategy, etc. are defined and planned.

  Software development activities shall be planned based on the template **T-200-1 Design Development Plan** according to the SOP-208 Software development.

  Special attention shall be drawn to the collaboration with the development and/or the manufacturing partner/supplier. Such suppliers shall be evaluated as defined in SOP-305.

  Detailed responsibilities shall be described in the Design & Development Plan and especially if collaborations is used. If a supplier / partner is involved in the development and/or the manufacturing, ASPIVIX SA must have access to all relevant documents. This must be secured through the quality assurance agreement set up between ASPIVIX SA and the supplier / partner (based on templates 305-3 and 305-4).

  Roles and responsibilities of each participant in the project as well as the need for their presence at the Design Reviews must be defined in the Design & Development Plan, T-200-1.
- For daily project management, the project is managed according to a Project Gantt Chart based on T-200-25.

During the planning phase, the intended use and the classification of the product and all related regulatory aspect have to be completed in the template T-200-8, Regulatory Product Requirements & pathway (RPR) and the Template T-200-5, General Safety & Performance Requirements (GSPR) has to be initiated. These documents are needed to initiate the following plan:

- **Risk Management and Usability Engineering Plan** (T-302-1) and,
- **Clinical Evaluation Plan (T-102-2).**

Technical Documentation

In this phase, the structure of the technical file (DHF and DMR) shall be defined based on the template T-200-2. The detailed content of the technical file depends on the type of product to be developed and therefore the project team is free to adjust / amend / adapt it to fit the specific product documentation needs.

As soon as the structure is defined, the documents that need to be established must be decided and listed in the Deliverables Matrix T-200-9. The Deliverables Matrix also embeds information of the responsible for the document.

It is the responsibility of the Project Leader to ensure:

- the establishment and maintenance of the technical documentation lies with the Project Leader.
- the effective and efficient communication and distribution of information between the team members, external parties and other functions participating in the development process.

The Technical Documentation structure is given by the template T-200-11. It contains the following chapters:

- A. EXECUTIVE SUMMARY
- B. TECHNICAL DOCUMENTATION
- C. TECHNICAL DOCUMENTATION ON PMS
- D. DECLARATION OF CONFORMITY
- E. DEVICE MARKET AUTHORITZATION – REGISTRATION – COUNTRY SPECIFIC
- F. REFERENCED DOCUMENT LOG

These chapters have a specific folder in which annexes of the technical documentation can refer to.

The documents log of the Technical Documentation tracks the last version of the referencing documents. The documents Log must be kept up to date.

The validated Technical Documentation is stored in the repository “Regulatory” > “Medical Device File – Technical documentation” > there is one dedicated folder per “Product/family product name”

Free and permanent access can be provided upon request by Competent Authority and/or Notified Body, via

specific shared point access secured by password on a cloud system.

2.1.2 DESIGN INPUT

2.1.2.1 Input for product design & development

Input for product design & development may originate from customers, clients and/or suppliers, as a result of internal requirements or from external sources as project request. The template Product Intended Use (T-200-26) defines the intended use of the product. Management, based on recommendations from the Head of Global Marketing, decides about project approval which is the start of the project. The template Marketing Requirement Specification, T-205-1 is recording the first intention / design of the product. In case the Design & Development process is outsourced; the detailed requirements of all parties shall be defined in a quality agreement development (see SOP-305).

In case the manufacturing activities are outsourced to third parties; the detailed requirements of all parties shall be defined in a supplier specification & quality agreement (see SOP-305).

Input for product design & development includes the intended use, customer requirements, functional and performance requirements, statutory and regulatory requirements, software requirements, product quality and performance objectives, and any other identified requirements.

Template **T-200-12 Design Input Requirements** is used to capture and define software requirements. Software requirements shall be referenced to applicable system requirements.

The following records will feed the Design Input Requirement (DIR), T-200-12:

- **User Requirements Specification** (URS), T-200-3
- **User Interface Requirements** (UIR), T-302-3
  Note: Usability specifications are combined with Hazyrd Assessment because the Usability Engineering process is combined with the risk management process.
- **General Safety & Performance Requirements** (GSPR), T-200-5
- **Regulatory Product Requirements & pathway** (RPR), T-200-8
- **Design Input Requirements,** T-200-12

The **Product Description (T-200-27)** document follows the approval of the Design Input Requirement, T-200-12. The product description reflects the information from the Design Input Requirement. Changes to The Design Input Requirements will determine the review of the corresponding version of the Product Description. The User Requirements specification and the **Traceability Matrix**, T-200-10, must be reviewed when there is a change to the Design Input Requirement.

The User Requirements Specification (URS) is the starting point for the development process and the input for establishing regulatory and normative requirements / Regulatory Pathway based on the template (RPR) T-200-8.

Based on the intended use, the medical device(s) shall be classified according to the applicable laws/regulations and guidance documents in the respective geographical area(s) where they shall be placed on the market. The intended use and classification shall be documented based on template T-200-8. Relevant regulatory requirements are defined in MDR 2017 / 745, MEDDEV Guidance 2.4/1, and the FDA Product Code Classification database based upon 21 CFR Parts 862-892.

The respective pathway to obtain market authorization shall be determined depending on the classification. If several pathways are possible, the least burdensome approach shall be chosen (unless otherwise defined by the CEO). Whether required, an Health Authority or a designated Body shall be involved to assess and approve the quality management system and/or the conformity assessment of the medical device(s) in question.

2.1.2.2 Input for product manufacturing

Input for product manufacturing processes includes product design output data, targets for productivity, capability, cost, and customer requirements, as applicable. Any experience or information from the market is applied as deemed appropriate.

The following records will feed the Design Input Requirement (DIR), T-200-12:

- **Marketing Requirements Specification** (MRS), T-205-1

- **Design & Development Plan** (DDP), T-200-1

At this stage ASPIVIX SA also establishes and approves the **Risk Management and Usability Engineering Plan** (T-302-1) as defined in SOP-302. A risk management is started according to ISO 14971.

2.1.2.3 Considerations for risk-based management

Applicable outputs of risk management will feed the DIR. **Outputs come from:**

- **Hazard Assessment**, T-302-3
- **Product Risk assessment**, T-302-4
- **Design & Process FMEA**, T-302-5

Traceability (verification and validation) of DIR related to risk management is performed in the **Traceability Matrix**, T-200-10. However:

- Outputs of Product Risk Assessment, T-302-4 related to DIR will be reported directly in the Traceability Matrix, then not in the DIR, to avoid double data entry.
- For the same reason, outputs of Design & Process FMEA, T-302-5 related to DIR are handled in the template T-302-5 because the risk control measures impact specifically the manufacturing specification, validation, and control. Hence it is not reported in the DIR but directly in the Traceability Matrix.

Design Input Requirements are defined based on the specification defined above as input for the design phase and are defined by ASPIVIX SA and documented based on template T-200-12. Critical supplier(s) shall contribute to and/or review the design input requirements if appropriate.

Design input requirements shall be unambiguous, clear, complete, correct, accurate, not conflicting, and testable.

Ambiguous, missing, unclear, incomplete, incorrect, or conflicting information is clarified and resolved with the request's originator before proceeding with the project. Alternatively, this can be done as part of a review in a team.

Design input requirements shall be reviewed as part of Design Review 1 (Design Input), and the above attributes shall be considered.

Records (including but not limited to those shown in the Design & Development Life-Cycle flowchart) shall be maintained as part of the DHF (Design History File).

ASPIVIX SA has approved the Clinical Evaluation Plan (T-102-2) at this stage.

2.2 DESIGN PHASE

In this phase, the design output shall be established depending on the setup and as defined in the Design & Development Plan. During the Design phase, Design Review 2 (Design Freeze) takes place. Deliverables prior to design freeze consist of the following (not exhaustive):

- Drawings, material, and part lists (T-200-23) and specifications, including safety data sheets (T-200-24)
- Application risk assessment (Hazard Assessment, T-302-3 and Product Risk Assessment, T-302-4)
- Design risk assessment (Design FMEA, T-302-5)
- Software development documentation
- Traceability Matrix (T-200-10)
- Verification and Validation Plan (T-200-6)

After the design has been frozen, the remaining tasks of the design phase shall be performed (not exhaustive):

- Design output specifications (based on T-200-22)
- Process risk assessment (Process FMEA, T-302-5)
- In-process control and final inspection instruction (based on the Design Specification sheet, T-200-24)
- Process Validation Plan (T-200-13)
- Quality Specification Agreement (T-305-3)
- Verification and Validation Test Specifications (refer to VVP)

The V&V test specifications are based on the approved verification and validation plan. The main rule is that every single user requirement is validated, and every single design input requirement is verified or assessed by at least one test case or evaluation. The planning must also contain the definition of acceptance criteria. Verification and validation readiness shall be confirmed as part of the Design Review 3 (V&V readiness) and above attributes shall

be taken into consideration.
The above mentioned released documents of the design phase are all part of the DHF. Availability and content of such documents shall be audited prior to product release.

All design software activities are part of the project. These activities are implemented according to process SOP-208 Software Development.

- **Product Maintenance**
  Many incidents in the field are related to maintenance of medical products/software including inappropriate software updates and upgrades. Because of that the product/software maintenance process is as important as the software development process. Software maintenance activities are described in INS-208-1 Software Maintenance.
- **Product Configuration Management**
  IEC 62304 standard identifies the software configuration management process as essential for developing safe medical software. Establish means to identify configuration items (software system and software configuration items are versioned through git and SourceTree tool). Identify system configuration documentation. Configuration items that comprise the software system configuration (including their versions) are tracked via deployment software tools. All software items, including Software Of Unknown Provenance (SOUPs) are recorded according to the procedure INS-208-2 Software Configuration Management. Software configuration is part of the device master record.
- Problem Resolution
  Another process important for the development of safe medical software is the software problem resolution process. Activities in this process are described in the INS-208-3 Software Problem Resolution Process. The Software Developer is obliged to monitor problem reports and track the problem resolution process. For actions needed to correct the problem a change request has to be filled in. All change requests approved by the Project Manager must be implemented by the development team.

2.3 VERIFICATION & VALIDATION PHASE

In this phase, design verification and validation, design transfer and process validation are performed. The completion of the phase shall be confirmed in Design Review 4 (V&V complete).

For more details, please refer to procedure **Validation Activities, SOP-206,** that defines the terms and media of the implementation of respective activities related to the products and the processes.

Software verification and validation activities are performed according to the SOP-208 Software Development.

2.3.1 VERIFICATION & VALIDATION

Verification and validation activities shall be performed as planned in the **Verification & Validation Plan** (based on T-200-6). The test and evaluation results shall demonstrate that the design output meets the design input requirements (design verification) and the user requirements (design validation). If a design input requirement or a user requirement is not fulfilled, a change of the acceptance criteria is only permitted if all applicable regulatory and safety requirements are met, and every change is justified.

- Software verification and validation activities are planned by utilizing the template T-200-6 Verification_Validation_Plan
- Outputs of these activities are reports based on the T-200-7_Verification_Validation_Summary_Report.

Verification of design input requirements and validation of the intended purpose of the medical device can be done internally and/or externally (Laboratory and Clinical testing). Examples of external verification and validation are testing in Laboratories according to IEC 60601-1, IEC 60601-1-2, Clinical investigation, etc.

Devices used in clinical investigation shall not be released on the market.

A **Traceability Matrix** (T-200-10) shall be established by ASPIVIX SA to ensure that the following requirements will be successfully verified and validated.

- All user requirements specifications (URS) must be translated into design input requirements.
- All marketing requirement specifications (MRS) must be translated into design input requirements.
- All user interface requirements (UIR) must be translated into design input requirements.
- All General Safety and Performance Requirements (GSPR) must be translated into design input requirements.

- All design input requirements (DIR) must be transferred into the Traceability Matrix.
- All risk controls by design /protective measures /information from Product Risk Assessment or D/P-FMEA must be transferred into the Traceability Matrix.

Labeling (instructions for use, labels, product labeling) shall be established based on applicable regulatory and normative requirements. SOP-306 shall be used. Specifically for EU market, the conformity of the CE marking shall be performed and verified in compliance of the instruction CE Marking Process, INS-200-2.

At this stage ASPIVIX SA will also establish and approve the Risk Management & Usability Engineering Report as defined in SOP-302.

Part of the design validation is a clinical evaluation. Requirements and format for a **clinical evaluation** are defined SOP-102 according to MEDDEV 2.7/1 revision 4.

The test and evaluation results shall be stored in the DHF. All results shall be summarized in a **Verification & Validation Summary Report** (based on T-200-7).

2.3.2 DESIGN TRANSFER

Design transfer ensures that the device design (design outputs) is correctly translated into commercial (suitable) **production specifications**[1] (based on Design Output Specification, T-200-22 and Design Specification sheet, T-200-24 and Drawings) to ensure that manufactured devices are repeatedly and reliably produced within product and process capabilities. The final version of the software needs to be documented according to the procedure SOP-208 Software Development.

The design outputs are the preliminary **Device Master Record** (DMR). The DMR is defined as a compilation of records containing the procedures and specifications for a finished device.

The design transfer is not an extra process but it's a process that may start along the design phase.

The **documentation required to start the design transfer**: all assembly drawings, bills of material (Nomenclature List), software documentation and code, special processes, inspection criteria, test criteria, acceptance criteria must be approved and released within the document control system. All procured materials/parts that will be employed in the manufacture of the newly designed medical device successfully pass First Article Inspection (FAI) and subsequent receiving inspection.
The documentation required for the design transfer should encompass the purchasing and receiving inspection processes specific to the newly designed device.

The design transfer process is guided by a set of questions in the Deliverable Matrix (T-200-9). The Design Transfer questionnaire states that the design specifications outputs are verified as suitable for manufacturing before becoming final production specifications and that production capacity can meet product requirements.

Availability and content of all documents shall be verified during Design Review, T-200-4.
If the Development is subcontracted, the data necessary to complete the transfer should be documented in the Design & Development Plan (T-200-1). The plan should document all necessary records to ensure the documentation is complete and supported by required verification and validation records. While it may be difficult to have a single checklist that covers all transfers within an organization with different kinds of medical devices, it still must be understood what is required to be reviewed.

Once design verification & validation testing is completed, the design transfer is finalized by reviewing and approving the product specifications based on a qualitative assessment of the completeness and adequacy of the production specifications. And it should ensure that only approved specifications are used to manufacture production devices. The two last elements are among the basic principles of document control and configuration management.

Respective activities shall be planned in the Design & Development Plan and reported in Design Reviews.

[1] ***Production specifications*** *include drawings and documents used to procure components, fabricate, test, inspect, install, maintain, and service the device.*

2.3.3 PROCESS VALIDATION

Process validation activities shall be performed as planned in a **Process Validation Plan** (based on T-200-13). All processes which cannot be or are not verified by subsequent monitoring or measurement require validation and, as a consequence, deficiencies become apparent only after the product is in use (including relevant computer systems used in production or service provision, if applicable). Validation shall demonstrate the ability of these processes to achieve planned results consistently.

Since ASPIVIX SA outsources manufacturing activities to qualified external suppliers, said suppliers need to provide objective evidence regarding planning, execution and reporting of process validation activities. ASPIVIX SA shall review and approve the validation packages for all processes where validation is required (e.g. input regarding acceptance criteria etc.).

Process validation activities shall be finalized prior to manufacturing products that are intended to be placed on the market. Depending on the specific context, process validation activities may need to be finalized for the devices that undergo design validation.

Software applications shall be validated prior to initial use and as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with using the software, including the effect on the ability of the product to conform to specifications.

Please refer to the instruction Software Validation, INS-205-1

Process Validation Reports (based on T-200-15) shall be stored in the DHF. In cases the process/computer system is used for various products, a reference shall be made from the DHF to the respective validation documentation. All results shall be summarized in a **Process Validation Summary Report** (based on T-200-14).

Availability and content of all documents shall be audited prior to product release.

The follow-up of manufacturing processes is performed and recorded in the DMR based on the **Process Traceability Matrix** T-200-16.

2.4 CONFORMITY ASSESSMENT PHASE

2.4.1 CONFORMITY ASSESSMENT

Prior to placing a device on the EU market and prior to putting into service a device that is not placed on the market, the design & development phase ends with a conformity assessment based on the previously established technical documentation (DHF and DMR). The assessment is performed according to the applicable conformity assessment procedures set out in the template T-200-8 Regulatory product Requirement & Pathway at the beginning of the design development.

In this context, the template, T-200-5, listing the General safety and performance Requirements shall be established and approved.

The Medical Device File (summarized in the STED and/or 510(k) for US market entry) is completed, reviewed, and approved.

If compliance with the applied regulatory requirements is ensured, the RAQM issues a Declaration of Conformity (draft) based on T-200-20. The Declaration of Conformity must not be signed until the respective EC certificate is granted by the Notified Body (except for class I products but it remains applicable for Class Is, Ir, Im).

The List of General Safety and Performance Requirements and the Declaration of Conformity are all part of the DHF.

2.4.2 REGISTRATION / MARKET AUTHORIZATION

In case a market authorization in a specified sales area requires a certification or registration, the records of the development phase will be worked up in the expected format and will be submitted to the relevant Notified Body or to the Competent Authority. To comply with most regions, it is preferably to establish the Technical Documentation in the format based on template T-200-11, but it can be adapted according to format Table of Content proposed by IMDRF/RPS WG/N9

2.5 MARKET PHASE

2.5.1 CHANGE MANAGEMENT

Post-market surveillance, field safety requirements, results of risk-analysis, ideas of product improvements and proposed changes (requested by internal departments and/or suppliers) may require, among others, corrective or preventive actions according to **procedure CAPA, SOP-104.**

rationales for issuance of change requests.

Changes to design specifications, once validated and accepted, must be subject to a formal change control process. The requests shall be reviewed and approved / rejected according to the procedure **Change Management, SOP-303**.

For the EU and US market, design changes that could potentially have significant effects on safety or performance must be reviewed to determine if a new 510(k) or a supplement to a PMA application will be required. Details regarding when to inform / consult the Notified Body or FDA are defined in the SOP-303.

The Project Leader shall define the responsibility for updating the technical documentation after project closure.

Details regarding change management with involved suppliers (such as detailed process, authorities, responsibilities, timelines etc.) shall be defined in the respective quality agreement with the supplier.

Change management is already **mandatory starting from Design Freeze.**

Not all changes are subject to the same level of design controls and validation or verification. To determine the level of effort that is necessary in controlling a change, please refer to SOP-303. Some considerations involved in determining the extent to which changes should be selected for design control – and when – are as follows:

- The initial design inputs need to be under control after they are approved.
- Change control is needed for devices undergoing clinical trials. A significant change in the design after the clinical devices are produced may invalidate the clinical data.
- After an element of a design is validated or verified and accepted, later changes need to be controlled., including re-verification and re-validation (as appropriate).
- A specification change that affects the finished device's benefit-risk balance needs careful assessment and planning of verification and validation to ensure that device safety is still acceptable.
- Change control requirement apply to any change to a device, its labeling or its packaging after it is released for production.
- Manufacturing processes, quality assurance procedures, and other elements of the DMR are also subject to design change control requirements.
- The level of verification and validation to be performed for subcontractor changes is based on the complexity and safety implications of the proposed change as well as on the internal quality assurance activities of the subcontractor. In all cases, configuration management and control of changes is essential.

2.5.2 POST-MARKET SURVEILLANCE / VIGILANCE AND COMPLAINT HANDLING

Complaints and Vigilance Reporting are described in SOP-103 and SOP-108, respectively.

Post-Market Surveillance is described in SOP-105.

2.6 DHF INDEX

References to the locations of the DHF documents, ensuring access to their most up-to-date versions:

-The traceability matrix in the DHF lists all Document Identification Records (DIR) and related test documents.

-The drawing list in the DMR contains the latest revisions of all drawings.

-The V&V Summary report lists all approved documents related to Verification and Validation (V&V), along with their latest revisions.

3 REFERENCES

3.1 PROCEDURES, INSTRUCTIONS AND GUIDELINES

[1] SOP-102 Clinical Evaluation
[2] SOP-103 Complaints Handling
[3] SOP-104 CAPA
[4] SOP-105 PMS
[5] SOP-108 Vigilance Reporting
[6] SOP-206 Validations Activities
[7] SOP-302 Risk Management & Usability Engineering
[8] SOP-303 Change Management
[1] SOP-305 Supplier Handling
[2] SOP-306 Labeling
[3] SOP-208 Software Development
[4] INS-208-1 Software Maintenance
[5] INS-208-2 Software Configuration Management
[6] INS--3 Software Problem Resolution
[7] MEDDEV 2.7/1 rev 4 - Clinical Evaluation: A Guide for Manufacturers and Notified Bodies
[8] IMDRF/RPS WG/N9 FINAL:2018 (Edition 2) - Non-In Vitro Diagnostic Device Market Authorization Table of Contents
[9] INS-205-1 Software Validation
[10] MDR 2017/745
[11] MEDDEV 2.4/1 rev.9 - Classification of medical devices
[12] FDA Product Code Classification database based upon 21 CFR Parts 862-892.
[13] INS-200-2 CE Marking Process

3.2 TEMPLATES AND FORMS

[14] T-102-2 Clinical Evaluation Plan
[15] T-200-1 Design & Development Plan
[16] T-200-2 Technical File – Table of Content
[17] T-200-3 User Requirements Specification
[18] T-200-4 Review Minutes
[19] T-200-5 GSPR
[20] T-200-6 Verification & Validation Plan
[21] T-200-7 Verification & Validation Summary Report
[22] T-200-8 Regulatory Product Requirement & Pathway
[23] T-200-9 Deliverables Matrix
[24] T-200-10 Traceability Matrix
[25] T-200-11 Technical Documentation (ToC)
[26] T-200-12 Design Input Requirements
[27] T-200-13 Process Validation Plan
[28] T-200-14 Process Validation Summary Report
[29] T-200-15 Process Validation Report
[30] T-200-16 Process Traceability Matrix
[31] T-200-17A Test Protocol
[32] T-200-18 Test Report List
[33] T-200-19 Investigator Brochure

[34] T-200-20 EU declaration of Conformity
[35] T-200-21 Standard Requirements Answer
[36] T-200-22 Design Output Specifications
[37] T-200-23 Drawings Nomenclature List
[38] T-200-24 Design Specifications Sheet
[39] T-200-25 Project Gantt Chart
[40] T-200-26 Product Intended Use
[41] T-200-27 Product Description
[42] T-302-1 Risk Management & Usability Engineering Plan
[43] T-302-3 Hazard
[44] T-302-4 Product Risk assessment
[45] T-302-5 Design & Process FMEA
[46] T-305-3 Quality Specification Agreement
[47] T-305-4 Quality Development Agreement
[48] T-200-17B Test Report

Aspivix SA | Route de la Corniche 8 | Bureau 10 | 1066 Epalinges | Switzerland

Certificate of Completion

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	Signature: f2060640fbaf5a7737313bd3b6c2be66147046650410eb3fccd5dc8d586d797d	
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	Signature: ffa7b3d5c84911a7ae23c5b0ac8b317bd8b5454f844565dc673887f4baa9fce1	
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Signature 	Aspivix SA, Mauro Rinaldi mauro.rinaldi@aspivix.com	03/28/2025 13:20:08
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