SOP-DND-006

Design and Development Verification - MD

Document status	Version history
State: Review	**Change History**

Approvals	Reviewer	Status	Date	Comment
Approval		PENDING		

Page Version	Date	Comment
Current Version (v. x)	<Date>	QA Manager

Signatures required

Signature required / meaning (Prepared by, Reviewed by, Approved by, Read and understood)	Function of signatories	Name of signatories

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Required signatories must e-sign the page

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References

ISO 13485:2016 — Clause 7.3.6 Design and Development Verification
Clause 7.3.6 says that verification activities are performed to confirm that design outputs fulfil design input requirements, and that objective evidence of these activities is retained.

Regulation (EU) 2017/745 (MDR) — General Safety and Performance Requirements (GSPR)

IEC 60601-1 / IEC 60601-1-2 — Electrical safety and EMC (where applicable)

IEC 62366-1 — Usability Engineering (where applicable)

1. Summary

This procedure defines how design and development verification activities are planned, performed, documented, and reviewed to ensure that design outputs meet defined design input requirements for Medical Devices.

Design and development verification provides objective evidence that the implemented design solutions fulfil specified requirements and contributes to demonstrating conformity with applicable MDR General Safety and Performance Requirements.

2. Scope

This procedure applies to all Medical Devices developed by the organization throughout the design and development lifecycle, from design output definition to readiness for design validation and subsequent development stages.

It covers verification of functional, performance, safety, and documentation-related design outputs.

3. Inputs

- Approved design input requirements
- Design and development plans
- Risk management outputs
- Applicable regulatory and normative requirements
- Design outputs and specifications

Design input requirements are defined and controlled in accordance with SOP-DND-003 Requirement and Inputs.

Design and development activities are planned and monitored in accordance with SOP-DND-002 Design and Development Planning.

4. Process Description

This process is part of the overall design and development lifecycle defined in SOP-DND-001 Product Realization Planning and interfaces with upstream and downstream design and development procedures.

4.1 Purpose of Design and Development Verification

Design and development verification confirms, through objective evidence, that design outputs correctly and completely implement approved design input requirements.

Verification is performed before design validation and supports progression through defined design review stages.

4.2 General Verification Process

4.2.1 Planning

Verification activities are planned in accordance with the design and development plan and include:

- Identification of appropriate verification methods
- Definition of acceptance criteria linked to design inputs
- Identification of required test environments and resources
- Update of the design traceability matrix to reflect planned verification activities

4.2.2 Execution

Verification activities are executed as planned and may include testing, inspection, analysis, and review activities. All results are:

- Documented contemporaneously
- Reviewed for completeness and accuracy
- Assessed against predefined acceptance criteria

Any deviations or nonconformities are documented and evaluated.

4.2.3 Analysis

Verification results are reviewed to:

- Confirm conformity with design input requirements
- Identify deviations, failures, or unexpected results
- Assess the potential impact on device safety, performance, and regulatory compliance

Where applicable, the risk analysis is reviewed and updated to reflect new information identified during verification.

The complete procedure is included in ReadySet

ISO 13485 QMS framework for Confluence – azbc.be