



**SOP Software  
Validation**

PROTOCOL NO.:

SUPERSEDE NO.:

DATE:

# **SOP Software Validation**

TITLE:	
AUTHORING GROUP:	
DATE:	
SUPERSEDE PROTOCOL NO.:	

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## SOP Software Validation

### Summary

This SOP ensures that the organization only works with validated computer/Software systems to avoid erroneous affecting the safety and performance of its medical devices. The process outlines requirements for validation before use.

**Process Owner** <enter role of process owner>

**Key Performance Indicators** <enter KPIs to be tracked for the Management Review>

**Regulatory References** ISO 13485: Sec. 4.1.6 and 6.3 and 7.6 IEC 62304:Sec. 9.8

### Process Steps

#### 1.1 Collecting Information and Preliminary Assessment

- Employee notifies QMO of the new system and provides the minimum information required for preliminary assessment, such as intended use description and preliminary risk estimation.
- QMO documents the intended use and determines whether the system is relevant for the QMS or the organization's medical devices as part of the computerized system validation form.
- If quality-relevant: continue to fill out the computerized system validation form (assessing critically and risks).
- If not quality relevant: document the system in the list of computerized systems and release the software system for use.

Responsible

Employee intending to work with the  
new system

QMO



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### Input

Information about the system  
Software Validation Form  
List of Software's

### Output

Preliminary Software Assessment

## 1.2 Plan Validation

- QMO continues to fill out the computerized system validation form by planning the validation and documenting the requirements for expected validation results.

Responsible

QMO

Input

Software Validation Form

Output

Updated Software Validation Form

## 1.3 Perform Validation

- Perform the validation based on the validation plan and fill out the validation report as part of the software validation form.
- Where appropriate, save additional proof of validation (e.g. screenshots) and add them to the validation report.

Responsible

Employee working with the system

Input

Software Validation Form

Output

Updated Software Validation Form

## 1.4 Release

If validation was not successful:

- Document the validation results in the list of computerized systems and classify the system as "blocked" / "not released for use".

If validation was successful:

- Document the validation results and sign the validation report as part of the computerized system validation form.
- Release the computerized system by adding it to the list of computerized systems.
- Inform relevant staff about the approval of the system.

Responsible

QMO

Input

Software Validation Form

Software List

Output

Completed Software Validation Form

Updated List of Software

Notification sent

### 1.5 Monitoring of Softwares

- User feedback and error reports by developers are monitored for relevant occurrences that may affect the organization or its medical devices.
- New version updates are implemented and the list of computerized systems is updated accordingly. If necessary, a revalidation is carried out.

Input

Error reports by users /  
developers

Output

Updated List of Software

If required: new record of Softwares  
Validation Form created

Responsible

QMO in collaboration with employee working with the system

### 1.6 Decommissioning of Software

- In case it is decided to decommission a computerized system, evaluate possible effects and document the actions in the list of Software.

Responsible

QMO

Input

Software Validation Form

Software List

Output

Updated List of Software