SOP Software Validation

Summary

This SOP ensures that the organization only works with validated computer/software systems to avoid erroneous systems 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 13485:2016 Sec. 4.1.6 and 6.3 and 7.6IEC 62304:2016 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 Software Validation Form.
- If quality-relevant: continue to fill out the Software Validation Form (assessing criticality and risks).
- If not quality-relevant: document the system in the Software List and release the software system for use.

Responsible	Employee intending to work with the new systemQMO
Input	Information about the systemSoftware Validation FormList of Software
Output	Preliminary Software Assessment

1.2 Plan Validation

- QMO continues to fill out the Software 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 Software 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 Software Validation Form.
- Release the software by adding it to the List of Software.
- Inform relevant staff about the approval of the system.

Responsible	QMO
Input	Software Validation FormList of Software
Output	Completed Software Validation FormUpdated List of SoftwareNotification 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 Software is updated accordingly. If necessary, a revalidation is carried out.

Responsible	QMO in collaboration with employee working with the system
Input	Error reports by users / developers
Output	Updated Software Validation FormIf required: new record of Softwares Validation Form created

1.6 Decommissioning of Software

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

Responsible	QMO
Input	Software Validation FormList of Software
Output	Updated List of Software
