# 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 |

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