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| C:\Users\GMP003\Downloads\logo of cyclone.jpg | **SOP Software Validation** | PROTOCOL NO.: |
| SUPERSEDE NO.: |
| DATE: |

**SOP Software**

**Validation**

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

**TABLE OF CONTENTS**

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No.** | **Contents** | | **Page No.** |
| **1** | **Process Steps** | |  |
|  | 1.1 | Collecting Information and Preliminary Assessment |  |
| 1.2 | Plan Validation |  |
| 1.3 | Perform Validation |  |
| 1.4 | Release |  |
| 1.5 | Monitoring of Software |  |
| 1.6 | Decommissioning of Software |  |

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

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

**Process Steps**

* 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 |

| Input | Output |
| --- | --- |
| Information about the system | Preliminary Software Assessment |
| Software Validation Form |  |
| List of Software’s |  |

* 1. **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 | Output |
| --- | --- |
| Software Validation Form | Updated Software Validation Form |

* 1. **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 | Output |
| --- | --- |
| Software Validation Form | Updated Software Validation Form |

* 1. **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 | Output |
| --- | --- |
| Software Validation Form | Completed Software Validation Form |
| Software List | Updated List of Software |
|  | Notification sent |

* 1. **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.

| Responsible |
| --- |
| QMO in collaboration with employee working with the system |

| Input | Output |
| --- | --- |
| Error reports by users / developers | Updated List of Software |
|  | If required: new record of Softwares Validation Form created |

**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 | Output |
| --- | --- |
| Software Validation Form | Updated List of Software |
| Software List |  |