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**Verification Validation Transfer Review Report Template!**

**Recipients**

|  |  |
| --- | --- |
| **Name** | **Function/Direction/Organism** |
| JOHN DOE | Independent reviewer |
| DR WHO | Clinical expert |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

**Purpose of the review:**

Review of ACME XXX Device VX.Y.Z for final release

**Summary of decisions**

|  |  |
| --- | --- |
| N° | Decision |
|  | **ACME XXX Device VX.Y.Z is approved for release provided that pending actions are completed.** |

**Summary of actions**

| N° | Action | Status | Who | Date |
| --- | --- | --- | --- | --- |
|  | Sign declaration of conformity when all other actions are closed |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

**Reviewed Documents**

|  |  |  |
| --- | --- | --- |
| **N°** | **Document ID / document name** | **Document Purpose** |
|  | ACME-SOFT-Technical File Index.docx | Technical file main document |
|  | ACME-SOFT-PMP Rev 01.docx | Project Management Plan |
|  | ACME-SOFT-IUS Rev 01.docx | Intended Use Statement |
|  | ACME-SOFT-RMP Rev 01.docx | Risk Management Plan |
|  | ACME-SOFT-RAR Rev 01.docx | Risk Assessment Report |
|  | ACME-SOFT-SRS Rev 01.docx | Software Requirement Specification |
|  | ACME-SOFT-SAD Rev 01.docx | Software Architectural Design |
|  | ACME-SOFT-USD Rev 01.docx | Usability Specification Document |
|  | ACME-SOFT-STP Rev 01.docx | Software Test Plan |
|  | ACME-SOFT-STR.xlsx | Software Test Report |
|  | ACME-SOFT-CER Rev 01.doc | Clinical Evaluation Report |
|  | ACME-SOFT-VDD Rev 01.doc | Version Delivery Description |
|  | ACME-SOFT-Labeling Rev 01.docx | Labeling Screenshot |
|  | ACME-SOFT-EU Class Rev 01.docx | EU classification rationale |
|  | ACME-SOFT-AHS Rev 01.docx | Applicable Harmonized Standards |
|  | ACME-SOFT-AER Rev 01.docx | Answers to Essential Requirements |
|  | ACME-SOFT-DOC Rev 01.docx | Declaration of CE Conformity |

**Meeting Minutes**

**Overview**

The meeting was held to verify and validate ACME XXX Device VX.Y.Z for release.

| **Question** | **Answer** | **Action** |
| --- | --- | --- |
| VERIFICATION |  |  |
| The design input review is documented in a report. |  |  |
| **Design steps:** |  |  |
| The customer requirements are recorded (notes taken during meetings, feedback from after-sales …). |  |  |
| The overall ergonomic principles are described in the USD. |  |  |
| The ergonomic principles in the USD have been translated into SRS requirements. |  |  |
| The SRS are up-to-date, are in line with customer requirements and have been validated. |  |  |
| The SAD is consistent with SRS. |  |  |
| The detailed design is consistent with architectural design. |  |  |
| The STP, is up-to-date and in line with the SRS. |  |  |
| All SRS have a test. |  |  |
| Each STR contains the status of all tests (OK, KO, not run). The last STR should have all tests OK, unless justified. |  |  |
| Each test marked as failed has a bug attached. |  |  |
| The unit tests cover all software units. |  |  |
| The integration and verification tests cover all SRS. |  |  |
| The VDD is up-to-date. |  |  |
| There is no bug with a level higher than minor, unless justified. |  |  |
| Open bug tracker tool issues other than those applicable to the product (eg issues found in surveillance of competitors’ products) have been reviewed for relevance to the product. |  |  |
| **Configuration management:** |  |  |
| The source code is tagged, saved, archived (build id, branch…). |  |  |
| SOUP Components are known (version, name ID), tagged, saved and archived. |  |  |
| **Risk management** |  |  |
| The RAR is up-to-date and in line with intended use. |  |  |
| Every risk related to human factors is listed in the RAR. |  |  |
| Every software risk is linked to a software element. |  |  |
| Every risk has a mitigation action. |  |  |
| Every software mitigation action is tested. |  |  |
| The unit tests cover all risk mitigation actions testable by this means. |  |  |
| The integration and verification tests cover all risk mitigation actions testable by this means. |  |  |
| The risks traceability matrixes are up-to-date and there is no blank cell is these matrixes, unless justified. |  |  |
| The known residual bugs don’t represent an unacceptable risk |  |  |
| **Usability, human factors engineering** |  |  |
| Formative evaluation reports are documented |  |  |
| Summative evaluation protocol and report are documented. The conclusion of the summative evaluation is positive with regard to risks. |  |  |
| **Problems resolution** |  |  |
| Each bug and/or enhancement is recorded in bug tracker tool. |  |  |
| The status of each tracker implemented in this version is set to closed. |  |  |
| Other trackers are not in an inconsistent status, like pending, fixed … |  |  |
| **Production/Deployment** |  |  |
| The list of production/deployment tests is well defined. |  |  |
| GUI Translations are validated. |  |  |
| Work instructions and other documentation for production and deployment are validated |  |  |
| **Design review** |  |  |
| The design output review (object of this checklist) is recorded in a report. |  |  |
|  |  |  |
| VALIDATION |  |  |
| **Essential Requirements** |  |  |
| All essential requirements have an answer. |  |  |
| Non-applicable essential requirements are listed, with a justification. |  |  |
| The document containing answers to essential requirements is up-to-date and in line with intended use. |  |  |
| **Clinical assessment** |  |  |
| There is a justification of method used for clinical assessment (literature search, clinical investigation…). |  |  |
| Scientific literature is defined and well referenced. |  |  |
| A document details methods or algorithms based on clinical literature used and/or implemented in the software. |  |  |
| The clinical evaluation report answers to criteria on essential requirements found in MEDDEV 2.7/1 rev.4. |  |  |
| **Instructions for Use** |  |  |
| IFU are consistent with the real behavior of software. |  |  |
| Residual risks are documented in IFU. |  |  |
| The identifier, the language, the CE mark, the ID of the notified body (if relevant), the date of CE mark, the name and address of manufacturer are up-to-date and documented in the IFU. |  |  |
| Contact of after-sales service (hotline, mail, …) are documented and up-to-date in IFU. |  |  |
| **Labeling – packaging**  |  |  |
| There is a template of packaging and labeling, with a validated "ready for printing" document. |  |  |
| The identifier, the language, the CE mark, the ID of the notified body, the date of CE mark, the name and address of manufacturer are up-to-date and documented in the packaging. |  |  |
| **Documentation** |  |  |
| The documentation is recorded in the directory of the project. |  |  |
| Documents are in their up-to-date version. |  |  |
| Front pages of documents are printed and signed. |  |  |
| Documentation is archived. |  |  |
| **CE Technical File is** |  |  |
| Up-to-date, or |  |  |
| If not 100% complete, actions of completion are defined and recorded, with a person responsible and an end date for each action. |  |  |
| **Intended use** |  |  |
| The device meets its intended use (give justification/evidence if appropriate, like meetings with clinicians, CER…). |  |  |
| **Participants** |  |  |
| A person with clinical expertise participated to the validation, whether directly (he/she was at the meeting) or through user testing or CER evaluation |  |  |
| A reviewer, independent of the design team participated to the validation. |  |  |
| **Meeting report** |  |  |
| The meeting report records the overall conclusion of the validation, of the fulfillment of user requirements, and of the risk / benefit ratio. | Yes, this report |  |
|  |  |  |
| TRANSFER |  |  |
| **Transferred Artifacts** |  |  |
| Transferred artifacts (version installation bundle, work instructions for production, user / admin / install manuals), are recorded in a VDD document |  |  |
| The VDD contains the non-ambiguous location of transferred artifacts |  |  |
| **Training to Customer Support** |  |  |
| The training to the customer support is defined and scheduled. |  |  |
|  |  |  |
| VERIFICATION, VALIDATION, AND TRANSFER |  |  |
| **Actions** |  |  |
| Deviations identified during this review are recorded. | Yes, actions list on first page |  |
| Actions are created with a person responsible and a deadline. | Yes, actions list on first page |  |
| Decision of the independent reviewer is recorded. | Yes, see above decision of JOHN DOE |  |
| **Meeting report** |  |  |
| A meeting report records relevant minutes of meeting, decisions and actions. | Yes, this report |  |

**Conclusions**

We conclude from the evidence in this meeting that ACME XXX Device VX.Y.Z for release, provided that pending actions are completed within two weeks.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Name | Date | Signature |
| Written by |  |  |  |
| Verified by |  |  |  |
| Approved by |  |  |  |
| Independent reviewer | JOHN DOE |  |  |