# Revision pane

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| **Revision** | **Date** | **Author** | **Notes** |
| 0 | 5/12/23 | GJGD | Draft for discussion |
| 1 | 2/12/23 | GJGD | Including document numbers following scheme in SSI-QF-10X |
| 2 |  | GJGD | Added SSI-QF-23A, moved SSI-QF-32C and 20G Plans to Plan section |

# Introduction

The aim of this document is to list the documents required for the development of a new device.

It combines the mandatory documents required as part of compliance with Stowood’s Total Quality Management system, Stowood’s engineering project documents from old projects (including the numbering system used on old projects where possible), and other documents that should be included.

It is arranged in rough order of creation where possible, although the exact order is difficult as it is anticipated that tasks may be simultaneous and ongoing.

This document could also form the basis of a document describing the anticipated schedule and/or overall status of the project.

# Table of documents

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Quality system document** | | **Project document number** | **Design doc. # from old projects** | **Engineering doc. from old projects** | **Other documents to be included** | **Notes** |
| 1. **Project definition phase** | | | | | | |
| SSI-QF-10Y Design project documents | |  |  |  | Document list | This document |
| SSI-QF-10Z Overall concept | |  |  |  | Overall concept |  |
| SSI-QF-10AA User journeys | |  |  |  | User journeys |  |
|  | 1. **Planning phase** | | | | | |
| SSI-QF-10O Project Management Quality Plan | |  |  |  |  |  |
| SSI-QF-10A Design and Development Plan | |  |  |  |  | Including:   * Overview of the project * Scope and objectives * Timeline and milestones (or as separate document) * Resource allocation |
| SSI-QF-10AB Project status report | |  |  |  | Project status report |  |
| SSI-QF-10G Design Change Record and Evaluation Form | |  |  |  | Project change request |  |
| SSI-QF-10D Design Traceability Matrix | |  |  |  |  |  |
| SSI-QF-13H Risk Management Plan | |  |  |  |  | Was designated “Visi-007” in Project 400 but needs a more future-proofed designation |
| SSI-QF-23A Strategy for regulatory compliance | |  |  |  |  |  |
| SSI-QF-23B Product classification | |  |  |  |  |  |
| SSI-QF-20A Software Safety Classification | |  |  |  |  |  |
| SSI-QF-25A Clinical Evaluation Plan | |  |  |  |  |  |
| SSI-QF-10H Design Plan Review | |  |  |  |  |  |
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|  | |  |  |  |  |  |
|  | 1. **Design Inputs Identification Phase** | | | | | |
| SSI-QF-10B Design Input Checklist | |  |  |  |  | Including:  1. Functional Requirements  2. Size, Weight, and Cost Requirements  3. Mechanical Requirements  4. Power Requirements  5. Thermal Requirements  6. Communication and Interface Requirements  7. Control Requirements  8. Computation Requirements  9. Software and Firmware Requirements  10. Data Storage, Format, Security Requirements  11. Precision and Accuracy Requirements  12. User Interface Requirements  13. Test and Validation Requirements  14. Electromagnetic Compatibility Requirements  15. Safety Requirements  16. Standards Requirements  17. Regulatory Requirements  18. Environmental Requirements  19. Materials Requirements  20. Patient or Clinical Requirements |
| SSI-QF-10AC Project risk register | |  |  |  | Project risk register |  |
| SSI-QF-20B Software Development Plan (was SSI-QF-10L) | |  |  |  |  |  |
| SSI-QF-20D Software Architecture Design | |  |  |  |  |  |
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|  | |  |  |  |  |  |
| SSI-QF-32A Use Specification | |  |  |  |  |  |
| SSI-QF-20C Software Requirements Specification and Traceability Matrix | |  |  |  |  | Firmware Requirements (software requirements) |
| SSI-QF-10C Design Review | |  |  |  |  |  |
|  | 1. **Design Output Documentation Phase** | | | | | |
| SSI-QF-32D Usability Evaluation Report | |  |  |  |  |  |
| SSI-QF-32E User Interface of Unknown Provenance (UOUP) | |  |  |  |  |  |
|  | |  |  |  |  |  |
| SSI-QF-13C Safety and Security Characteristics Checklist | |  |  |  |  |  |
| SSI-QF-13E Design Failure Mode and Effects Analysis (DFMEA) | |  |  |  |  |  |
| SSI-QF-13F Process Failure Mode and Effects Analysis (PFMEA) | |  |  |  |  |  |
|  | |  |  |  |  |  |
| SSI-QF-13G Safety and Security Characteristics Checklist | |  |  |  |  |  |
| SSI-QF-34A Information Security Risk Analysis | |  |  |  |  |  |
|  | |  |  |  |  |  |
| SSI-QF-10G Design Change Record and Evaluation Form | |  |  |  |  |  |
| SSI-QF-10AD Block diagram of main systems | |  |  |  | Block diagram of main systems |  |
| SSI-QF-10AE Schematic | |  | nn0-60 | Schematic |  |  |
| SSI-QF-10AF PCBs | |  | nn0-00 to nn0–79 | PCB |  |  |
| SSI-QF-10AG Mechanical drawings | |  |  | mechanical drawings |  | enclosure, accessories, test jigs |
| SSI-QF-10AH Packaging | |  |  | packaging |  |  |
| SSI-QF-10AI Bill of materials | |  | nnn-85-89 | Bills of Materials |  |  |
| SSI-QF-10AJ Power budget | |  |  |  | Power budget |  |
| SSI-QF-20K Software/ firmware code | |  |  |  | Software/ firmware code |  |
| SSI-QF-2J Critical supplier agreement | |  |  |  | Supplier agreements |  |
| SSI-QF-2I Supplier rating form | |  |  |  | Supplier audit reports |  |
| SSI-QF-2K Supplier and Material certificates/ datasheets | |  |  |  | Supplier and Material certificates/ datasheets |  |
| SSI-QF-14E Labels | |  |  |  | Device labels including serial numbers, packaging, hook up cards, product brochures, component cards |  |
|  | |  |  |  |  |  |
| SSI-QI-3I Assembly procedure | |  | nnn-90 to nnn-99 | reserved for Standard Work Instructions |  | Programming, Production, assembly, |
| SSI-QF-12A Packaging | |  |  |  |  | packaging |
| SSI-QF-14B Labelling Approval Form | |  |  |  |  |  |
| SSI-QF-14F Instructions for use | |  | nn0-100 | Instructions for Use |  | In various languages |
| SSI-QF-14G Change log for instructions for use | |  |  |  | Change log for IFU |  |
| SSI-QF-14C Instructions for Use Checklist | |  |  |  |  |  |
| SSI-QF-10C Design Review | |  |  |  |  |  |
|  | 1. **Design Verification Phase** | | | | | |
| SSI-QF-10I Test Procedure | |  |  |  |  | Mechanical tests, electrical tests, safety tests, transport tests, biological tests, 60601 tests |
|  | |  |  |  |  |  |
| SSI-QF-20E Software Test Protocol | |  |  |  |  |  |
| SSI-QF-20F Software Test Report | |  |  |  |  |  |
| SSI-QF-20H Software Maintenance Report | |  |  |  |  |  |
| SSI-QF-20K Software Checklist (was SSI-QF-10J) | |  |  |  |  |  |
| SSI-QF-20L Software Build Numbers Summary of Changes (was SSI-QF-10N) | |  |  |  |  |  |
| SSI-QF-20M Firmware Programmable Part Release (was SSI-QF-10S) | |  | nnn-95 | PRN (programmable release note) |  |  |
| SSI-QF-20J Software Release Version Control (was SSI-QF-10F) | |  |  |  |  |  |
| SSI-QF-20I Software Summary Report | |  |  |  |  |  |
|  | |  |  |  |  |  |
| SSI-QF-10P Problem Report Hardware and Software | |  |  |  |  |  |
| SSI-QF-10V Research Testing Protocol Template | |  |  |  |  |  |
| SSI-QF-10R Design Verification or Validation Protocol | |  |  |  |  |  |
|  | |  |  |  |  |  |
| SSI-QF-10Q Design Verification or Validation Report | |  |  |  |  |  |
| SSI-QF-10T MDR Compliance Checklist | |  |  |  |  |  |
| SSI-QF-10U DHF Verification | |  |  |  |  |  |
| SSI-QF-14A Labelling Development and Verification Checklist (MDR) | |  |  |  |  |  |
| SSI-QF-10C Design Review | |  |  |  |  |  |
|  | 1. **Design Validation Phase** | | | | | |
| SSI-QF-25B Clinical Evaluation Report | |  |  |  |  |  |
| SSI-QF-32B Usability Engineering File | |  |  |  |  |  |
| SSI-QF-10R Design Verification or Validation Protocol | |  |  |  |  |  |
| SSI-QF-10Q Design Verification or Validation Report | |  |  |  |  |  |
| SSI-QF-13D Risk Management Report | |  |  |  |  |  |
| SSI-QF-22B General Safety and Performance Requirements (GSPRs) | |  |  |  |  |  |
| SSI-QF-22A Technical Documentation | |  |  |  |  |  |
| SSI-QF-10K Checklist for Creating a Technical File | |  |  |  |  |  |
| SSI-QF-10C Design Review | |  |  |  |  |  |
|  | 1. **Design Transfer** **Phase** | | | | | |
| SSI-QF-10W Device Master Record | |  |  |  |  |  |
| SSI-QF-10E Design Transfer Checklist | |  |  |  |  |  |
|  | |  |  |  |  |  |
| SSI-QF-10M Declaration of Conformity EUMDD (DoC) | |  |  |  |  |  |
| SSI-QF-22C Declaration of Conformity EUMDR (DoC) | |  |  |  |  |  |
| SSI-QF-13A Post Production Information Review | |  |  |  |  |  |

# References

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