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| --- | --- | --- | --- |
| **Issue** | **Date** | **Author** | **Change description** |
| 3 | 29/11/02 | WLD | Control Procedure to ISO 13485:1996 |
| 4 | 03/11/03 | SRM | Include Canadian device regulations |
| 5 | 10/1/04 | WLD | Amended following SGS Document Review |
| 6 | 26/1/06 | BJB | Update for ISO13485:2003 |
| 7 | 28/4/08 | WLD | Addition of life cycle and Software version recording |
| 8 | 1/3/10 | TJW | Updated for FDA 21 CFR part 820. Manual header/footer/naming revised. |
| 9 | 14/2/12 | wld | Addition to section 3.2, 3.4 & rearrangement of other parts |
| 10 | 14/2/14 | CK | Reallocation of CEO and Technical Manager responsibilities |
| 11 | 11/03/15 | JF | Remove references to US and Canadian regulations; re-allocate certain responsibilities to reflect new staff and organisation structure |
| 12 | 12/08/15 | GJGD | Updated to standardise naming conventions and add reference to SSI-QF-10K to 10M |
| 13 | 23/05/16 | GJGD | Updated to include procedure for identifying significant changes requiring notification to the notified body |
| 14 | 10/06/16 | JF/GJGD | Addition of requirement to consider effect of any design change on existing devices. |
| 15 | 31/05/17 | JF | Clarify what constitutes a design change and actions to follow. |
| 16 | 1/12/17 | JF/GJGD | Updated to comply with ISO 13485:2016 |
| 17 | 26/2/18 | GJGD | Updated to give further instructions for Class I registration and changes |
| 18 | 26/3/19 | GJGD | Includes reference to Quality Plan and form SSI-QF-10O Quality Plan |
| 19 | 28/2/20 | GJGD | Includes references to existing documents, made more prescriptive |
| 20 | 14/04/22 | JF | Amended to conform to requirements of 17/745/MDR. Introduced form SSI-QF-10T MDR Compliance Checklist - added section 3.11. Amended MHRA device registration procedure 3.2. |
| 21 | 08/05/23 | JF | Major revision of the design and development process with updated and new associated design forms in line with the MDR and MDSAP regulatory requirements. Added instruction to use SSI-QF-10L for device classification. Removed reference to MHRA. Combined Design Verification and Validation into one form SSI-QF-10Q iss3. SSI-QF-10R up-issued to iss 2 as Verification or Validation Protocol. |
| 22 | 23/10/23 | JF | In the last upissue reference to registering devices with MHRA were removed (old section 3,2) but SSI-QI-10A Registering a Medical Device with MHRA has not been moved or changed. The contents of SSI-QI-10A have now been added to SSI-SOP-26 EUDAMED Registration, which has been renamed to include MHRA registration.  Device Classification is now covered under SSI-SOP-23 Strategy For Regulatory Compliance. As a result SSI-QF-10L becomes SSI-QF-23B Device Classification under EUMDR and UKMDR  As software development is now covered in SSI-SOP-20 software forms have been moved to SSI-SOP-20:  SSI-QF-10F becomes SSI-QF-20J Software Release Version Control  SSI-QF-10J becomes SSI-QF-20K Software Checklist  SSI-QF-10N becomes SSI-QF-20L Software Build Numbers Summary of Changes  SSI-QF-10S becomes SSI-QF-20M Firmware Programmable PartRelease  Included all quality forms - QF-10A to QF-10W - in list of references.  Withdrawn - SSI-QI-10A, SSI-QC-10A; SSI-QF-10F, SSI-QF-10J, SSI-QF-10L SSI-QF-10N and SSI-QF-10S.  SSI-QF-10B and QF-10U had been given each other’s title now reversed: SSI-QF-10B Design Input Checklist, SSI-QF-10U Design History File Verification.  SSI-QF-10P Problem Report is retained in SSI-SOP-10 as it records both hardware and software problems |
| 23 | 14/12/23 | GJGD | Updated to include more design document templates. Populated SSI-QF-10Y Design Project Documents |
| 23 | xx.06.25 | JF | Added SSI-QF-10AL Protocol for the Functionality Test Covering the Life of the Device |

Approved:…GJGD…………. ……..

(CEO)

Date:……..…xx062024…………

1. Purpose

The purpose and scope of this procedure is to define the design and development process for medical devices manufactured by Stowood Scientific Instruments Ltd (Stowood).

This procedure is intended to ensure compliance with the appropriate sections of ISO 13485:2016, the European Medical Device Directive 93/42 EEC (EUMDD), EU MDR 2017/745 (EUMDR), U.S. FDA Quality System Regulations 21 CFR 820.30 (21CFR), UK Medical Device Regulations (UKMDR) and SOR/98-282 Canadian Medical Device Regulations (SOR/98-282).

1. Scope

This procedure applies to the design and development of new medical devices as well as to design changes to existing devices.

This procedure does not cover requirements for design and development of software, which is undertaken in accordance with **SSI-SOP-20 Software Development.**

1. Responsibilities
   1. CEO/Project Lead:
      1. Leads and monitors the various phases, reviews the overall project progress.
      2. Ensures team members are trained to relevant SOPs
      3. Ensures completion of the required activities per this SOP.
      4. Leads the design review process and ensures that design review action items are documented and completed.
   2. Project team:
      1. Each member of the project team is responsible to develop and execute the activities as defined in **SSI-QF-10A Design and Development Plan.**
   3. Independent Reviewer:
      1. Provides an independent confirmation that the design and development process meets the requirements of this SOP. Independent Reviewers (who may be consultants) have no direct responsibilities for the process but are required attendees for design reviews. Independent reviewers must have sufficient qualifications, knowledge and experience to provide credible confirmation that the process requirements are being met.
2. References
   1. SSI-SOP-9 Record Control
   2. SSI-SOP-13 Risk Management
   3. SSI-SOP-14 Labelling
   4. SSI-SOP-17 Post Market Surveillance and Post Market Clinical Follow Up,
   5. SSI-SOP-20 Software Development
   6. SSI-SOP-22 Creation and Maintenance of Technical Documentation
   7. SSI-SOP-25 Clinical Evaluation
   8. SSI-SOP-32 Usability Engineering
   9. SSI-QF-10A Design and Development Plan
   10. SSI-QF-10B Design Input Checklist
   11. SSI-QF-10C Design Review
   12. SSI-QF-10D Design Traceability Matrix
   13. SSI-QF-10E Design Transfer Checklist
   14. SSI-QF-10F see SSI-QF-20J
   15. SSI-QF-10G Design Change Record and Evaluation Form
   16. SSI-QF-10H Design Plan Review
   17. SSI-QF-10I Test Procedure
   18. SSI-QF-10J see SSI-QF-20K
   19. SSI-QF-10K Checklist for Creating a Technical File
   20. SSI-QF-10L see SSI-QF-23B
   21. SSI-QF-10M EUMDD Declaration of Conformity Form
   22. SSI-QF-10N see SSI-QF-20L
   23. SSI-QF-10O Project Management Quality Plan template
   24. SSI-QF-10P Problem Report Hardware and Software
   25. SSI-QF-10Q Design Verification or Validation Report
   26. SSI-QF-10R Design Verification or Validation Protocol
   27. SSI-QF-10S see SSI-QF-20M
   28. SSI-QF-10T MDR Compliance Checklist
   29. SSI-QF-10U DHF Verification
   30. SSI-QF-10V Research Testing Protocol Template
   31. SSI-QF-10W Device Master Record
   32. SSI-QF-10X Development Project Document numbering scheme
   33. SSI-QF-10Y Design project documents
   34. SSI-QF-10Z Overall concept
   35. SSI-QF-10AA User journeys
   36. SSI-QF-10AB Project status report
   37. SSI-QF-10AC Project risk register
   38. SSI-QF-10AD Block diagram of main systems
   39. SSI-QF-10AE Schematic
   40. SSI-QF-10AF PCB
   41. SSI-QF-10AG Mechanical drawings
   42. SSI-QF-10AH Packaging
   43. SSI-QF-10AI Bills of materials
   44. SSI-QF-10AJ Power budget
   45. SSI-QF-10AK Design documentation template
   46. Protocol for the Functionality test Covering the Life of the Device
   47. SSI-QI-10O Determining conformity assessment route for medical devices EUMDR
3. Definitions
   1. Design Input - the physical and performance requirements of a device that are used as a basis for device design. **SSI-QF-10B Design Input Checklist** should contain all the requirements including user, product, software and hardware requirements.
   2. Design Output - the results of design activity at each design phase and at the end of the design process. The finished design output consists of the device, its packaging and labelling and is contained in the **Device Master Record SSI-QF-10W**.
   3. Design Review - a documented, comprehensive, systematic examination of design to evaluate the adequacy of the design requirements, to evaluate the capability of the design to meet these requirements, and to identify problems, captured on **SSI-QF-10C Design Review.**
   4. Design Verification - Confirmation by examination and testing with provision of objective evidence that the specified requirements have been fulfilled – see **SSI-QF-10Q Design Verification or Validation Report.**
   5. Design Validation - establishing by objective evidence that device specifications meet user needs and intended use(s) and can be consistently fulfilled - **SSI-QF-10Q Design Verification or Validation Report.**
   6. Design History File (DHF) - Compilation of the records which describes the design history of a device - see section 7.9.
   7. Device Master Record (DMR) – a compilation of records containing the specification and procedures to manufacture a device - see **SSI-QF-10W.**
   8. Design and Development Changes - Design and development changes made to the product after the product has been released for manufacturing. Note: Design changes made during the design and development process shall be evaluated under this procedure.
   9. GSPR - General Safety and Performance Requirements of the EUMDR
   10. Human Factors Engineering / Usability Engineering / Usability: The application of knowledge about human behaviour, abilities, limitations, and other characteristics of medical device users to the design of medical devices including mechanical and software driven user interfaces, systems, tasks, user documentation, and user training to enhance and demonstrate safety, effectiveness, efficiency, ease of user learning and user satisfaction.
   11. Risk Management File - a compilation of records or references to all documented risk management activities in accordance with **SSI-SOP-13 Risk Management**
   12. Specification - any requirement with which a product, process, service, or other activity must conform.
4. Procedure

**General Requirements:**

* 1. The process of design and development at SSI is divided into 6 phases follows:
  + Phase I: Design and Development Planning
  + Phase II: Design Inputs
  + Phase III: Design Outputs
  + Phase IV: Design Verification
  + Phase V: Design Validation
  + Phase VI: Design Transfer
  1. Clinical evaluation, risk management, usability, biological evaluation, software validation and other product bench testing are integral sub-processes that affect the design and development, together with labelling, instructions for use and process validation. See **SSI-SOP-13 Risk Management**, **SSI-SOP-14 Labelling, SSI-SOP-20 Software Development, SSI-SOP-25 Clinical Evaluation**, **SSI-SOP-32 Usability Engineering.**
  2. All deliverables for each design and development phase must have been completed before the phase design review takes place. Activities in different phases may start simultaneously, as appropriate.

1. PROCEDURE:
   1. Design documents should be written from the template SSI-QF-10AK Design document template as a guide.
   2. **Phase 0: Project definition phase**
      1. The project can be documented using **SSI-QF-10Y Design project documents**.
      2. The overall concept can be documented in **SSI-QF-10Z Overall concept**
      3. To aid colleague understanding, the user journeys can be described in **SSI-QF-10AA User journeys.**
   3. **Phase I: Design and Development Planning; User Requirements**
      1. The design and development activities must be planned using **SSI-QF-10A Design and Development Plan**, the design and development plan must describe or reference the design and development activities and define responsibility for implementation. It must also identify and describe the methods for traceability of design outputs to design inputs, resources and competence needed and the interfaces with different groups or activities that provide, or result in, input to the design and development process.
      2. The design and development plan must be reviewed and re-approved for any updates as design and development progresses, and at least at the end of each design phase.
      3. As applicable, software classification and requirements must be determined and documented in line with **SSI-SOP-20** **Software Development** and **SSI-QF-20B Software Development Plan** and **SSI-QF-20A Software Safety Classification.**
      4. User requirements may be derived from emails, meetings, seminars, phone calls, contracts, product drawings, market surveys, research, benchmarking results or industry practice. Records of user requirements must be maintained in the Design History File - see 7.9.
      5. Preliminary User Needs must be reviewed and approved using **SSI-QF-10D Design Traceability Matrix** (User Needs) column at the end of Phase I.
      6. Refer to **SSI-QF-10U DHF Verification** for the minimum requirements that must be completed prior to the design review and moving to the next phase.
   4. **Phase II: Design Inputs**
      1. The purpose of Phase II is to translate user requirements into specific Design Inputs to address the function, performance, usability and safety requirements of the device in accordance with its intended use and user needs.
      2. The process of developing Design Inputs must consider the following:
   * Requirements specified by the customer/end-user.
   * Requirements not specified by the customer/end-user but necessary for the intended use, as far as known.
   * Applicable regulatory requirements, harmonized standards, Common Specifications, other applicable guidance documents such as FDA guidance documents or Medical Device Coordination Group (MDCG) guidance documents
   * Any user training needs.
   * Outputs of risk management activities on similar devices or outputs of preliminary risk assessment on the device under development.
   * Information derived from previous similar designs.
     1. The Usability Engineering process shall follow **SSI-SOP-32 Usability Engineering**. Earlyevaluations and determination of use specifications for the device may help generate design inputs.
     2. Country-specific regulatory requirements shall be determined in line with the regulatory strategy documented as part of **SSI-QF-10A Design and Development Plan** and any country-specific requirements and inputs relevant to the device function and safe usage shall be met. For example: General Safety and Performance Requirements (GSPRs) in the European Union, Essential Requirements in the UK, Safety and Effectiveness Requirements in Canada.
     3. Any change to the user needs and intended use that affect the Design Input must be addressed. Also, any change to the Design Input must be evaluated for its effect on user needs and intended use.
     4. All User Needs and Design Inputs must be reviewed and approved to ensure they are complete, unambiguous and compatible with each other using **SSI-QF-10D Design Traceability Matrix**, (User Needs) and (Design Inputs) columns at the end of Phase II.
     5. Refer to **SSI-QF-10U DHF Verification**, for requirements that must be completed prior to the design review and moving to the next phase.
   1. **Phase III: Design Outputs** 
      1. Design outputs are created during this phase. Examples of design and development outputs include specifications of the material, component parts and sub-assemblies and finished devices, packaging and labelling, purchasing requirements, process specifications, assembly and inspection work instructions, work environment requirements, monitoring and measuring equipment needs, and engineering drawings.
      2. The design outputs must be referenced in **SSI-QF-10D Design Traceability Matrix,** (Design Outputs) column. The Design Traceability Matrix must be reviewed and approved by the Project Team at the end of Phase III.
      3. Refer to **SSI-QF-10U DHF Verification**, for the minimum requirements that must be completed prior to the design review and moving to the next phase.
   2. **Phase IV: Design Verification**
      1. The design verification phase is intended to confirm via verification activities that the design outputs meet the design inputs with reference to predetermined acceptance criteria.
      2. Design verifications must include the following:
   * Verification of the product requirement(s).
   * Description of the verification method used and any consideration of harmonized standards, common specifications and consensus standards, as applicable.
   * Identification of the design (part number and revision, with lot number if applicable).
   * Justification of the device that was used in the analysis, including worst case selection, if applicable.
   * Acceptance criteria, appropriately justified. The justifications should include reference to standards, internal procedures, technical specifications, published literature, or predicate or equivalent device verification, as applicable.
   * Sample size justification.
   * Deviations from the protocol, if applicable.
   * Raw data from the verification.
   * Conclusion statement confirming whether the test results met (or failed) the acceptance criteria.
   * Date performed.
   * Individual(s) responsible for performing the verification.
     1. The design verification should follow **SSI-QF-10R Design Verification or Validation Protocol** and the conclusions documented and approved on **SSI-QF-10Q Design Verification or Validation Report**
     2. Sample size justification may be based on standards. If no suggestions for sample size exist in standards, the sample size must be based on risk by reviewing the project risk documentation and determining the probability and severity of harm for the product requirements to be met. The highest rated probability and severity of harm must be assumed.
     3. Design verification must be conducted on initial production units, lots, or batches. or their equivalents. If production units or production equivalents cannot be used, the design verification protocol and report must include an explanation of the differences, along with a justification for why the differences would not affect the results and validity of the verification activity.
     4. Design verification must be conducted with manufacturing and test equipment calibrated, maintained and controlled according to **SSI-SOP-5 Test and Measuring Control.**
     5. If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), the design verification must include confirmation that the design outputs meet design inputs when it is connected or interfaced.
     6. Examples of design verification records include but are not limited to: performance testing, electrical safety testing, software verification.
     7. The design verification report numbers must be referenced in **SSI-QF-10D Design Traceability Matrix** and in **SSI-QF-10Q Design Verification or Validation Report** in the last column. The **Design Traceability Matrix** must be reviewed and approved at the end of Phase IV.
     8. If any of the design inputs need to be changed after design verification has been conducted, the effect on the verification activity must be evaluated, and if necessary, verification must be repeated, or a rationale must be provided for not doing so. The rationale must be approved by the project team and maintained in the Design History File see 7.9.
     9. Refer to **SSI-QF-10U DHF Verification Form** for the minimum requirements that must be completed prior to the design review and moving to the next phase.
   1. **Phase V: Design Validation** 
      1. Design validation must be traceable to defined User Needs and ensure that devices meet defined User Needs and intended uses under actual or simulated use conditions. Design validation must also confirm that potential for use error has been mitigated.
      2. Design validation must address the whole medical device and its components, and interfaces as well as its packaging, labelling and Instructions for Use (IFU).
      3. Design validation must include the following:
   * The defined User Need(s).
   * Description of the validation method used and any consideration of harmonized /, common or consensus standards.
   * Identification of the design (part number and revision, with lot number if applicable).
   * Justification for which device was used in the analysis, including worst case selection, if applicable.
   * Acceptance criteria, appropriately justified. The justifications should include reference to standards, internal procedures, technical specifications, published literature, or predicate or equivalent device validation testing, as applicable.
   * Description of validation participants, including justification of how the participants are representative of the user population and justification of the sample size of each user group.
   * Any deviations from the validation protocol.
   * Raw data from the validation.
   * Conclusion statement confirming whether the design validation met (or failed) the acceptance criteria.
   * Date performed.
   * Individual(s) responsible for performing the validation.
     1. The design validation protocols must follow **SSI-QF-10R Design Verification or Validation Protocol** and its conclusions must be documented and approved using **SSI-QF-10Q Design Verification or Validation Report.**
     2. Design validation must be conducted on initial production units, lots, or batches, or their equivalents. If production units or production equivalents cannot be used, the design validation protocol and report must include an explanation of the differences, along with a justification for why the differences would not affect the results and validity of the validation activity.
     3. As part of design and development validation for a device to be placed on the EU market a clinical evaluation must be performed in accordance with **SSI-SOP-25 Clinical Evaluation.**
     4. If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), the design validation must be met when it is so connected or interfaced.
     5. If software is part of the design, the design validation must include software validation and risk analysis in accordance with **SSI-SOP-20 Software Development**.
     6. Design validation can also include analysis and inspection methods via appropriate pre-clinical laboratory evaluation and/or animal testing and/or full clinical investigations/clinical trials.
     7. Summative usability testing, human factors design validation activities should also be conducted to ensure that the potential for use error during critical tasks has been reduced to as far as possible, in accordance with **SSI-SOP-32 Usability Engineering**.
     8. Risk management documentation must be updated to include any new hazards or harms identified during validation and their mitigation.
     9. The results of the validation processes must be fed back into each phase of the design and development process, as this can lead to changes and improvements (or into the next design and development revision, or next generation of the product).
     10. The design validation report numbers must be referenced in the project **SSI-QF-10D Design Traceability Matrix** (Design Validation) column. The **Design Traceability Matrix** must be reviewed and approved by the project team at the end of Phase V.
     11. Refer to **SSI-QF-10U DHF Verification** the minimum requirements that must be completed prior to the design review and moving to the next phase.
   1. **Phase VI: Design Transfer** 
      1. The purpose of phase VI is to transfer the design from the validation phase to full-scale production, to demonstrate manufacturability of the device, and to complete preparations for product commercialization and market launch.
      2. The design transfer phase must ensure the following requirements are met:
   * All required manufacturing and inspection procedures and work instructions are created and approved, and any product drawings are approved.
   * The transferred design is fully documented in **SSI-QF-10W Device Master Record** (DMR).
   * Manufacturing specifications are established including all BOMs and production and inspection records in accordance with **SSI-SOP-3 Manufacture, Inspection and Test**.
   * All validation requirements and any test method validations have been met.
   * The Risk Management File is completed in accordance with **SSI-SOP-13 Risk Management**.
   * Suppliers are qualified in accordance with **SSI-SOP-2 Purchasing and accepting goods and services**
   * Ensuring adequate resources have been allocated and all required training is complete.
   * Ensuring availability of parts and materials.
   * Ensuring availability of production, test and inspection equipment and tools, calibrated, validated and maintained.
   * Approving final product and package labelling and IFU, and any promotional materials in accordance with the **SSI-SOP-14 Labelling procedure**
     1. Objective evidence provided for each deliverable, such as **SSI-QF-10E Design Transfer Checklist** may be used and filed with the Design History File –see 7.9.
     2. Refer to the **SSI-QF-10U DHF Verification** for the requirements that must be completed prior to the design review of the Transfer Phase.
     3. Commercial release of the product cannot begin until the following is fulfilled
   * Regulatory approval is received for the countries in which the product is intended to be sold.
   * All documentation required as part of the Design History File is created and any correction, corrective actions or, deviation resolutions are completed and approved.
   * **SSI-QF-10M EUMDD Declaration of Conformity** for the device has been issued.
   * Post Market Surveillance Plan and Post Market Clinical Follow-Up Plan, as applicable, are approved in accordance with **SSI-SOP-17 Post Market Surveillance and Post-Market Clinical Follow-Up** for devices to be placed in the EU market.
   1. **Design Reviews**
      1. Phase design reviews must be planned and conducted at the end of each design and development phase prior to moving to the next development phase.
      2. The participants in each phase design review must include representatives of all functions concerned with the design phase being reviewed and an independent reviewer.
      3. All required deliverables for that phase must have been completed and documented. Work on subsequent phases may proceed while earlier phases are in progress. However subsequent phases cannot be approved until all earlier phases are completed and approved.
      4. The results of a design review, including identification of the design, the date, problems, action items and the individual(s) performing the review, must be documented and approved using **SSI-QF-10C Design Review,**
   2. **Design Changes** 
      1. A design change is any change that affects the conformity of a device to the approved product specifications, user needs or intended use(s). Design changes include among other things changes to material, configuration, labelling, principle of operation, manufacturing process, quality attributes or supplier.
      2. Changes must be initiated using **SSI-QF-10G Design Change Record and Evaluation Form** on which its effect on function, performance, safety and usability of the product will be evaluated.
      3. The design changes must be assessed for its effect on the following:
   * User needs
   * Product specifications (design inputs)
   * Design outputs
   * Design verification and validation
   * Inspection, or assembly procedures
   * Risk Management File.
   * Technical documentation, regulatory filing and/or application.
     1. Design changes must be reviewed, verified, validated, as appropriate and approved before implementation.
   1. **Design History File (DHF)**
      1. The Design History File must contain or reference all the records necessary to demonstrate conformity with **SSI-QF-10A Design and Development Plan.**
      2. A DHF must be established and maintained for a product line, a product family or an individual device.
      3. The DHF must include or reference the minimum elements as follows:
   * **SSI-QF-10A Design and Development Plan**
   * Results of engineering, laboratory, simulated use and other tests
   * **SSI-QF-10Q Design Verification or Validation Reports**
   * **SSI-QF-10R Design Verification or Validation Protocol**
   * **SSI-QF-10D Design Traceability Matrix**
   * **SSI-QF-10C Design Reviews**
   * **SSI-QF-10U DHF Verification** for each phase
   * Risk Management File per **SSI-SOP-13 Risk Management**
   * **SSI-QF-10W Device Master Record**
   * **SSI-QF-17K Post Market Surveillance Plan**
   * **SSI-QF-17J Post Market Clinical Follow-Up Plan**
   * **SSI-QF-10G Design Change Record and Evaluation** for all design changes
     1. Elements of the design history file are outputs to the device family technical documentation. See **SSI-SOP-22 Creation and Maintenance of Technical Documentation.**
2. PRODUCT CLASSIFICATION

8.1 This is covered in SSI-SOP-23 Strategy for Regulatory Compliance, section 6, which details classification rules to be followed in different jurisdictions. To determine the classification of a device under the EUMDR or UKMDR Stowood uses form SSI-QF-23B Device Classification. This form should be completed carefully with explanations in reasonable detail as to why particular classification rules apply or do not apply to the device, the classification decision should be noted on the form, and the form filed as a quality record.

Authorisation to train others and to modify SOP.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Who is authorised to train others (add to training record) | | | Authorised to modify SWI (add to training record) | | |
| **Who is authorised to train** | **Authorised by** | **Date authorised** | **Who is authorised to modify** | **Authorised by** | **Date authorised** |
| GJGD | GJGD | 1/1/23 | GJGD | GJGD | 1/1/23 |
| JF | GJGD | 1/1/23 | JF | GJGD | 1/1/23 |
|  |  |  |  |  |  |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Initial training | | Training on document. Mark date of training under the issue number of document you are trained on. | | | | | | |
| **Major change? If yes add to training log** | | **Y** |  | **Y** |  |  |  |  |
| **Trainee** | **Trainer** | **21** | **22** | **23** |  |  |  |  |
| Gwilym Davies | GJGD | 8/5/23 | 30/10/23 | 14/12/13 |  |  |  |  |
| Paul Gladding | GJGD | 8/5/23 | 30/10/23 | 14/12/23 |  |  |  |  |