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| TEST REPORT **IEC 62304**  **Medical device software**  **Software life-cycle processes** | | |
|  | |  |
| **Report Number. :** | |  |
| **Date of issue :** | | **2016.02.26** |
| **Total number of pages** | |  |
| **Applicant’s name :** | **METABIOMED CO., LTD** | |
| **Address :** |  | |
| **Test specification:** |  | |
| **Standard :** | IEC 62304:2006 (First Edition) | |
| **Test procedure :** | CB Scheme | |
| **Non-standard test method :** | N/A | |
| **Test Report Form No. :** | IEC62304B | |
| **Test Report Form(s) Originator :** | IMQ S.p.A. | |
| **Master TRF :** | Dated 2013-02 | |
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| **Test item description :** |  | |
| **Trade Mark :** |  | |
| **Manufacturer :** |  | |
| **Model/Type reference :** |  | |
| **Ratings :** |  | |
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| Testing procedure and testing location: | | | | |
|  | | **CB Testing Laboratory:** |  | |
| **Testing location/ address :** | | |  | |
|  | | **Associated CB Testing Laboratory:** |  | |
| **Testing location/ address :** | | |  | |
|  | **Tested by (name + signature) :** | |  |  |
|  | **Approved by (name + signature) :** | |  |  |
|  | | | | |
|  | | **Testing procedure: TMP** |  | |
| **Testing location/ address :** | | |  | |
|  | **Tested by (name + signature) :** | |  |  |
|  | **Approved by (name + signature) :** | |  |  |
|  | | | | |
|  | | **Testing procedure: WMT** |  | |
| **Testing location/ address :** | | |  | |
|  | **Tested by (name + signature) :** | |  |  |
|  | **Witnessed by (name + signature) :** | |  |  |
|  | **Approved by (name + signature) :** | |  |  |
|  | | | | |
|  | | **Testing procedure: SMT** |  | |
| **Testing location/ address :** | | |  | |
|  | **Tested by (name + signature) :** | |  |  |
|  | **Approved by (name + signature) :** | |  |  |
|  | **Supervised by (name + signature) :** | |  |  |
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| List of Attachments (including a total number of pages in each attachment): | |
| **Summary of testing:** | |
| **Tests performed (name of test and test clause):** | **Testing location:** |
| **Summary of compliance with National Differences**  **List of countries addressed:**  **The product fulfils the requirements of \_\_\_\_\_\_\_\_\_ (insert standard number and edition and delete the text in parenthesis or delete the whole sentence if not applicable)** | |

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| **Copy of marking plate**  **The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.** |

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| **Calibration:** | All instruments used in the tests given in this test report are calibrated and traceable to national or international standards.  Further information about traceability will be given on request. |
| **Measurement uncertainty:** | Measurement uncertainties are calculated for all instruments and instrument set-ups given in this report. Calculations are based on the principles given in the standard EA-4/02 (Dec. 1999), IEC Guide 115:2007, Nemko routine L227 and other relevant internal Nemko-procedures.  Further information about measurement uncertainties will be given on request. |
| **Evaluation of results:** | If not explicitly stated otherwise in the standard, the test is passed if the measured value is equal to or below (above) the limit line, regardless of the measurement uncertainty. If the measured value is above (below) the limit line, the test is not passed - ref IEC Guide 115:2007, and Nemko routine L220. The instrumentation accuracy is within limits agreed by IECEE-CTL (ref. Nemko routine L227). |

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| **Test item particulars :** |  |
| **Classification of installation and use :** |  |
| **Type of end product :** |  |
| **End product :** |  |
| **Trademark :** |  |
| **End product model and/or type reference :** |  |
| **End product manufacturer :** |  |
| **End product address :** |  |
| **End product rating(s) :** |  |
| **Software designer (if different than end product manager) :** |  |
| **Address :** |  |
| **Method of identification of software (e.g. revision level, date of release/issue) :** |  |
| **Software classification :** | A, B, C |
| **Particular risks addressed by software :** |  |
| **Possible test case verdicts:** |  |
| **- test case does not apply to the test object :** | N/A |
| **- test object does meet the requirement :** | P (Pass) |
| **- test object does not meet the requirement :** | F (Fail) |
| **Testing :** |  |
| **Date of receipt of test item :** |  |
| **Date (s) of performance of tests :** |  |
|  | |
| **General remarks:** | |
| The test results presented in this report relate only to the object tested. This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory. "(See Enclosure #)" refers to additional information appended to the report. "(See appended table)" refers to a table appended to the report.  **Throughout this report a  comma /  point is used as the decimal separator.** | |
| **Manufacturer’s Declaration per sub-clause 4.2.5 of IECEE 02:** | |
| The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided : | **Yes**  **Not applicable** |
| **When differences exist; they shall be identified in the General product information section.** | |
| **Name and address of factory (ies) :** |  |
| General product information: | |

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| **4** | **GENERAL REQUIREMENTS** | |  |
| 4.1 | [A, B, C] The manufacturer of medical device software demonstrated the ability to provide medical device software that consistently meets customer requirements and applicable regulatory requirements. | *Software Validation Report*  *Q5-29-028*  *8.3 Software Configuration Management Life Cycle* | P |
| 4.2 | [A, B, C] The manufacturer applied a risk management process complying with ISO 14971. | *Software Validation Report*  *Q5-29-028*  *3. Risk Management* | P |
| 4.3 | [A, B, C] SOFTWARE SAFETY CLASSIFICATION | |  |
|  | a) The manufacturer assigned to each software system a software safety class (A, B, or C) according to the possible effects on the patient, operator, or other people resulting from a hazard to which the software system can contribute. | *Software Validation Report*  *Q5-29-028*  *1. Level of concern* | P |
|  | The software safety classes were initially assigned based on severity as follows: | |  |
|  | Class A: No injury or damage to health is possible | *Software Validation Report*  *Q5-29-028*  *1. Level of concern* | P |
|  | Class B: Non-serious injury is possible | *Software Validation Report*  *Q5-29-028*  *1. Level of concern* | P |
|  | Class C: Death or serious injury is possible |  | N/A |
|  | If the hazard could arise from a failure of the software system to behave as specified, the probability of such failure was assumed to be 100 per cent. | *Software Validation Report*  *Q5-29-028*  *3. Risk Management* | P |
|  | If the risk of death or serious injury arising from a software failure is subsequently reduced to an acceptable level (as defined by ISO 14971) by a hardware risk control measure, either by reducing the consequences of the failure or by reducing the probability of death or serious injury arising from that failure, the software safety classification may be reduced from C to B; |  | N/A |
|  | If the risk of non- serious injury arising from a software failure is similarly reduced to an acceptable level by a hardware risk control measure, the software safety classification may be reduced from B to A. | *Software Validation Report*  *Q5-29-028*  *1. Level of concern* | P |
|  | b) The manufacturer assigned to each software system that contributes to the implementation of a risk control measure a software safety class based on the possible effects of the hazard that the risk control measure is controlling. | *Software Validation Report*  *Q5-29-028*  *3. Risk Management* | P |
|  | c) The manufacturer documented the software safety class assigned to each software system in the risk management file | *Software Validation Report*  *Q5-29-028*  *3. Risk Management* | P |
|  | d) When a software system is decomposed into software items, and when a software item is decomposed into further software items, such software items inherit the software safety classification of the original software item (or software system) unless the manufacturer documents a rationale for classification into a different software safety class. | *Software Validation Report*  *Q5-29-028(4*  *3. Risk Management* | P |
|  | A rationale explains how the new software items are segregated so that they may be classified separately | *Software Validation Report*  *Q5-29-028(4*  *3. Risk Management* | P |
|  | e) The manufacturer documented the software safety class of each software item if that class is different from the class of the software item from which it was created by decomposition | *Software Validation Report*  *Q5-29-028(4*  *3. Risk Management* | P |
|  | f) Wherever a process is required for software items of a specific classification and the process is necessarily applied to a group of software items, the manufacturer used the processes and tasks which are required by the classification of the highest-classified software item in the group unless the manufacturer documents in the risk management file a rationale for using a lower classification | *Software Validation Report*  *Q5-29-028*  *1. Level of concern* | P |
|  | g) For each software system, until a software safety class is assigned, Class C requirements applied |  | N/A |

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| **5** | **SOFTWARE DEVELOPMENT PROCESS** | |  |
| 5.1 | SOFTWARE DEVELOPMENT PLANNING | |  |
| 5.1.1 | [A, B, C] The manufacturer established a software development plan (or plans) for conducting the activities of the software development process appropriate to the scope, magnitude, and software safety classifications of the software system to be developed. | *Software Validation Plan*  *Q5-29-028(01)*  *5. Software Development Process* | P |
|  | The software development life cycle model was either fully defined or be referenced in the plan (or plans). | *Software Validation Plan*  *Q5-29-028(01)*  *5.4 Development Life Cycle Procedure* | P |
|  | The plan is address the following:L | |  |
|  | a) the processes to be used in the development of the software system | *Software Validation Plan*  *Q5-29-028(01)*  *5.4 Development Life Cycle Procedure* | P |
|  | b) the deliverables (includes documentation) of the activities and tasks | *Software Validation Plan*  *Q5-29-028(01)*  *5. Software Development Process* | P |
|  | c) traceability between system requirements, software requirements, software system test, and risk control measures implemented in software | *Software Validation Plan*  *Q5-29-028(01)*  *5. Software Development Process* | P |
|  | d) software configuration and change management, including soup configuration items and software used to support development | *Software Validation Plan*  *Q5-29-028(01)*  *5. Software Development Process* | P |
|  | e) software problem resolution for handling problems detected in the software products, deliverables and activities at each stage of the life cycle | *Software Validation Plan*  *Q5-29-028(01)*  *5. Software Development Process* | P |
| 5.1.2 | [A, B, C] The manufacturer updated the plan as development proceeds as appropriate | *Software Validation Plan*  *Q5-29-028(01)*  *5. Software Development Process* | P |
| 5.1.3 | [A, B, C] Software development plan reference to system design and development | | P |
|  | a) As inputs for software development, system requirements are referenced in the software development plan by the manufacturer | *Software Validation Plan*  *Q5-29-028(01)*  *5. Software Development Process* | P |
|  | b) The manufacturer included or referenced in the software development plan procedures for coordinating the software development and the design and development validation necessary to satisfy 4.1 | *Software Validation Plan*  *Q5-29-028(01)*  *5. Software Development Process* | P |
| 5.1.4 | [C] Associated with the development of software items of class C, in the software development plan are included or referenced: | | N/A |
|  | a) standards |  | N/A |
|  | b) methods |  | N/A |
|  | c) tools |  | N/A |
| 5.1.5 | [B, C] The manufacturer included or referenced in the software development plan, a plan to integrate the software items (including soup) and perform testing during integration | *Software Validation Plan*  *Q5-29-028(01)*  *5. Software Development Process* | P |
| 5.1.6 | [A, B, C] In the software development plan, the following verification information are included or referenced: | | P |
|  | a) deliverables requiring verification | *Software Validation Plan*  *Q5-29-028(01)*  *12. Software Verification & Validation Plan* | P |
|  | b) the required verification tasks for each life cycle activity | *Software Validation Plan*  *Q5-29-028(01)*  *12. Software Verification & Validation Plan* | P |
|  | c) milestones at which the deliverables are verified | *Software Validation Plan*  *Q5-29-028(01)*  *12. Software Verification & Validation Plan* | P |
|  | d) the acceptance criteria for verification of the deliverables | *Software Validation Plan*  *Q5-29-028(01)*  *12. Software Verification & Validation Plan* | P |
| 5.1.7 | [A, B, C] The manufacturer included or referenced in the software development plan, a plan to conduct the activities and tasks of the software risk management process, including the management of risks relating to soup | *Software Validation Plan*  *Q5-29-028(01)*  *11 Risk Management Plan* | P |
| 5.1.8 | [A, B, C] The manufacturer included or referenced in the software development plan information about the documents to be produced during the software development life cycle. | *Software Validation Plan*  *Q5-29-028(01)*  *13. Software Configuration Management Plan* | P |
|  | For each identified document or type of document the following information must be included or referenced: | | P |
|  | a) title, name or naming convention | *Software Validation Plan*  *Q5-29-028(01)*  *13. Software Configuration Management Plan* | P |
|  | b) purpose | *Software Validation Plan*  *Q5-29-028(01)*  *13. Software Configuration Management Plan* | P |
|  | c) intended audience of document | *Software Validation Plan*  *Q5-29-028(01)*  *13. Software Configuration Management Plan* | P |
|  | d) procedures and responsibilities for development, review, approval and modification | *Software Validation Plan*  *Q5-29-028(01)*  *13. Software Configuration Management Plan* | P |
| 5.1.9 | [A, B, C] The manufacturer included or referenced software configuration management information in the software development plan. | *Software Validation Plan*  *Q5-29-028(01)*  *8. Resource Management Plan* | P |
|  | The software configuration management information must include or reference: | |  |
|  | a) the classes, types, categories or lists of items to be controlled | *Software Validation Plan*  *Q5-29-028(01)*  *8. Resource Management Plan* | P |
|  | b) the software configuration management activities and tasks | *Software Validation Plan*  *Q5-29-028(01)*  *8. Resource Management Plan* | P |
|  | c) the organization(s) responsible for performing software configuration management and activities | *Software Validation Plan*  *Q5-29-028(01)*  *8.1 Role and Responsibility* | P |
|  | d) their relationship with other organizations, such as software development or maintenance | *Software Validation Plan*  *Q5-29-028(01)*  *8.2 Project Term Organization* | P |
|  | e) when the items are to be placed under configuration control | *Software Validation Plan*  *Q5-29-028(01)*  *9. Project Schedule* | P |
|  | f) when the problem resolution process is to be used | *Software Validation Plan*  *Q5-29-028(01)*  *10. Project Deliverables* | P |
| 5.1.10 | [B, C] The items to be controlled include tools, items or settings, used to develop the medical device software, which could impact the medical device software | *Software Validation Plan*  *Q5-29-028(01)*  *3. Definition of Terms* | P |
| 5.1.11 | [B, C] The manufacturer plans to place configuration items under documented configuration management control before they are verified | *Software Validation Plan*  *Q5-29-028(01)*  *6. Software Documents* | P |
| 5.2 | SOFTWARE REQUIREMENTS ANALYSIS | |  |
| 5.2.1 | [A, B, C] For each software system of the medical device, the manufacturer defined and documented software system requirements from the system level requirements | *Software Validation Report*  *Q5-29-028*  *4. Software Requirements Specification* | P |
| 5.2.2 | [A, B, C] As appropriate to the medical device software, the manufacturer included in the software requirements: | |  |
|  | a) functional and capability requirements | *Software Validation Report*  *Q5-29-028*  *4.1 Hardware Requirements* | P |
|  | b) software system inputs and outputs | *Software Validation Report*  *Q5-29-028*  *4.3 Interface Requirements* | P |
|  | c) interfaces between the software system and other systems | *Software Validation Report*  *Q5-29-028*  *4.3 Interface Requirements* | P |
|  | d) software-driven alarms, warnings, and operator messages | *Software Validation Report*  *Q5-29-028*  *4.1.5 Safety features* | P |
|  | e) security requirements | *Software Validation Report*  *Q5-29-028*  *4.1.7 External equipment* | P |
|  | f) usability engineering requirements that are sensitive to human errors and training | *Software Validation Report*  *Q5-29-028*  *4.1.5 Safety features* | P |
|  | g) data definition and database requirements | *Software Validation Report*  *Q5-29-028*  *4.3.5 Functions for checking DB size & compaction DB* | P |
|  | h) installation and acceptance requirements of the delivered medical device software at the operation and maintenance site or sites | *Software Validation Report*  *Q5-29-028*  *4.1.3 Sensors* | P |
|  | i) requirements related to methods of operation and maintenance | *Software Validation Report*  *Q5-29-028*  *4.1.6.9 Mode Selection* | P |
|  | j) user documentation to be developed | *Software Validation Report*  *Q5-29-028*  *4.3.9 CP (Patient)* | P |
|  | k) user maintenance requirements | *Software Validation Report*  *Q5-29-028*  *4.4.2 Internal software tests and checks* | P |
|  | l) regulatory requirements | *Software Validation Report*  *Q5-29-028*  *9.3.1 Regulatory Standards* | P |
| 5.2.3 | [B, C] The manufacturer included risk control measures implemented in software for hardware failures and potential software defects in the requirements as appropriate to the medical device software | *Software Validation Report*  *Q5-29-028*  *4. Software Requirements Specification* | P |
| 5.2.4 | [A, B, C] The manufacturer re-evaluated the medical device risk analysis when software requirements are established and update it as appropriate | *Software Validation Report*  *Q5-29-028*  *4. Software Requirements Specification* | P |
| 5.2.5 | [A, B, C] The manufacturer ensures that existing requirements, including system requirements, are re-evaluated and updated as appropriate as a result of the software requirements analysis activity | *Software Validation Report*  *Q5-29-028*  *4. Software Requirements Specification* | P |
| 5.2.6 | [A, B, C] The manufacturer verified and documented that the software requirements: | | P |
|  | a) implement system requirements including those relating to risk control | *Software Validation Report*  *Q5-29-028*  *4. Software Requirements Specification* | P |
|  | b) do not contradict one another | *Software Validation Report*  *Q5-29-028*  *4. Software Requirements Specification* | P |
|  | c) are expressed in terms that avoid ambiguity | *Software Validation Report*  *Q5-29-028*  *4. Software Requirements Specification* | P |
|  | d) are stated in terms that permit establishment of test criteria and performance of tests to determine whether the test criteria have been met | *Software Validation Report*  *Q5-29-028*  *4. Software Requirements Specification* | P |
|  | e) can be uniquely identified | *Software Validation Report*  *Q5-29-028*  *4. Software Requirements Specification* | P |
|  | f) are traceable to system requirements or other source | *Software Validation Report*  *Q5-29-028*  *4. Software Requirements Specification* | P |
| 5.3 | SOFTWARE ARCHITECTURAL DESIGN | |  |
| 5.3.1 | [B, C] The manufacturer transformed the requirements for the medical device software into a documented architecture that describes the software’s structure and identifies the software items | *Software Validation Report*  *Q5-29-028(4*  *5. Architecture Design Chart* | P |
| 5.3.2 | [B, C] The manufacturer developed and documented an architecture for the interfaces between the software items and the components external to the software items (both software and hardware), and between the software items | *Software Validation Report*  *Q5-29-028(4*  *5. Architecture Design Chart* | P |
| 5.3.3 | [B, C] If a software item is identified as soup, the manufacturer specified functional and performance requirements for the soup item that are necessary for its intended use | *Software Validation Report*  *Q5-29-028*  *5. Architecture Design Chart* | P |
| 5.3.4 | [B, C] If a software item is identified as soup, the manufacturer specified the system hardware and software necessary to support the proper operation of the soup item | *Software Validation Report*  *Q5-29-028*  *5. Architecture Design Chart* | P |
| 5.3.5 | [C] The manufacturer identified the segregation between software items that is essential to risk control, and state how to ensure that the segregation is effective |  | N/A |
| 5.3.6 | [B, C] The manufacturer verified and document that: | |  |
|  | a) the architecture of the software implements system and software requirements including those relating to risk control | *Software Validation Report*  *Q5-29-028*  *5.1 Software Diagram and Description* | P |
|  | b) the software architecture is able to support interfaces between software items and between software items and hardware | *Software Validation Report*  *Q5-29-028*  *5. Architecture Design Chart* | P |
|  | c) the medical device architecture supports proper operation of any soup items |  | N/A |
| 5.4 | SOFTWARE DETAILED DESIGN | |  |
| 5.4.1 | [B, C] The manufacturer refined the software architecture until it is represented by software units | *Software Validation Report*  *Q5-29-028(4*  *5. Architecture Design Chart* | P |
| 5.4.2 | [C] The manufacturer developed and documented a detailed design for each software unit of the software item |  | N/A |
| 5.4.3 | [C] The manufacturer developed and documented a detailed design for any interfaces between the software unit and external components (hardware or software), as well as any interfaces between software units |  | N/A |
| 5.4.4 | [C] The manufacturer verified and documented that the software detailed design: | | N/A |
|  | a) implements the software architecture |  | N/A |
|  | b) is free from contradiction with the software architecture |  | N/A |
| 5.5 | SOFTWARE UNIT IMPLEMENTATION AND VERIFICATION | |  |
| 5.5.1 | [A, B, C] The manufacturer implemented each software unit | *Software Validation Report*  *Q5-29-028*  *8.1.1 Development Life Cycle Procedure* | P |
| 5.5.2 | [B, C] The manufacturer established strategies, methods and procedures for verifying each software unit | *Software Validation Report*  *Q5-29-028*  *8.1.1 Development Life Cycle Procedure* | P |
|  | Where verification is done by testing, the test procedures were evaluated for correctness. | *Software Validation Report*  *Q5-29-028*  *8.1.1 Development Life Cycle Procedure* | P |
| 5.5.3 | [B, C] The manufacturer established acceptance criteria for software units prior to integration into larger software items as appropriate, and ensure that software units meet acceptance criteria | *Software Validation Report*  *Q5-29-028*  *8.1.1 Development Life Cycle Procedure* | P |
| 5.5.4 | [C] When present in the design, the manufacturer included additional acceptance criteria as appropriate for: | | N/A |
|  | a) proper event sequence |  | N/A |
|  | b) data and control flow |  | N/A |
|  | c) planned resource allocation |  | N/A |
|  | d) fault handling (error definition, isolation, and recovery) |  | N/A |
|  | e) initialisation of variables |  | N/A |
|  | f) self-diagnostics |  | N/A |
|  | g) memory management and memory overflows |  | N/A |
|  | h) boundary conditions |  | N/A |
| 5.5.5 | [B, C] The manufacturer performed the software unit verification and documented the results | *Software Validation Report*  *Q5-29-028*  *9 Verification and Validation Documentation* | P |
| 5.6 | SOFTWARE INTEGRATION AND INTEGRATION TESTING | |  |
| 5.6.1 | [B, C] The manufacturer integrated the software units in accordance with the integration plan (see 5.1.5) | *Software Validation Report*  *Q5-29-028*  *9. Verification and Validation Documentation* | P |
| 5.6.2 | [B, C] The manufacturer verified and recorded the following aspects of the software integration in accordance with the integration plan (see 5.1.5): | | P |
|  | a) the software units have been integrated into software items and the software system | *Software Validation Report*  *Q5-29-028*  *6. Software Design Specification(SDS)* | P |
|  | b) the hardware items, software items, and support for manual operations of the system have been integrated into the system | *Software Validation Report*  *Q5-29-028*  *6. Software Design Specification(SDS)* | P |
| 5.6.3 | [B, C] The manufacturer tested the integrated software items in accordance with the integration plan (see 5.1.5) and documented the results | *Software Validation Report*  *Q5-29-028*  *6. Software Design Specification(SDS)* | P |
| 5.6.4 | [B, C] For software integration testing, the MANUFACTURER addressed whether the integrated SOFTWARE ITEM performs as intended | *Software Validation Report*  *Q5-29-028*  *9. Verification and validation Documentation* | P |
| 5.6.5 | [B, C] The manufacturer evaluated the integration test procedures for correctness | *Software Validation Report*  *Q5-29-028*  *9.5.1 Static Analysis* | P |
| 5.6.6 | [B, C] When software items are integrated, the manufacturer conducted regression testing appropriate to demonstrate that defects have not been introduced into previously integrated software | *Software Validation Report*  *Q5-29-028*  *11. Unsolved Bugs* |  |
| 5.6.7 | [B, C] The manufacturer: | |  |
|  | a) documented the test result (pass/fail and a list of anomalies) | *Software Validation Report*  *Q5-29-028*  *8.1.1 Development Life Cycle Procedure* | P |
|  | b) retains sufficient records to permit the test to be repeated | *Software Validation Report*  *Q5-29-028*  *8.1.1 Development Life Cycle Procedure* | P |
|  | c) identified the tester | *Software Validation Report*  *Q5-29-028*  *8.1.1 Development Life Cycle Procedure* | P |
| 5.6.8 | [B, C] The manufacturer entered anomalies found during software integration and integration testing into a software problem resolution process | *Software Validation Report*  *Q5-29-028*  *9.2 Definitions* | P |
| 5.7 | SOFTWARE SYSTEM TESTING | |  |
| 5.7.1 | [B, C] The manufacturer established and performed a set of tests, expressed as input stimuli, expected outcomes, pass/fail criteria and procedures, for conducting software system testing, such that all software requirements are covered | *Software Validation Report*  *Q5-29-028*  *8. Software development Environment Description* | P |
| 5.7.2 | [B, C] The manufacturer entered anomalies found during software system testing into a software problem resolution process | *Software Validation Report*  *Q5-29-028*  *8. Software development Environment Description* | P |
| 5.7.3 | [B, C] When changes are made during software system testing, the manufacturer: | |  |
|  | a) repeated tests, perform modified tests or perform additional tests, as appropriate, to verify the effectiveness of the change in correcting the problem. | *Software Validation Report*  *Q5-29-028*  *8. Software development Environment Description* | P |
|  | b) conducted testing appropriate to demonstrate that unintended side effects have not been introduced | *Software Validation Report*  *Q5-29-028*  *8. Software development Environment Description* | P |
|  | c) performed relevant risk management activities as defined in 7.4 | *Software Validation Report*  *Q5-29-028*  *8. Software development Environment Description* | P |
| 5.7.4 | [B, C] The manufacturer verified that: | |  |
|  | a) the verification strategies and the test procedures used are appropriate | *Software Validation Report*  *Q5-29-028*  *9. Verification and Validation Documentation* | P |
|  | b) software system test procedures trace to software requirements | *Software Validation Report*  *Q5-29-028*  *9. Verification and Validation Documentation* | P |
|  | c) all software requirements have been tested or otherwise verified | *Software Validation Report*  *Q5-29-028*  *9. Verification and Validation Documentation* | P |
|  | d) test results meet the required pass/fail criteria | *Software Validation Report*  *Q5-29-028*  *9. Verification and Validation Documentation* | P |
| 5.7.5 | [B, C] The manufacturer: | |  |
|  | a) document the test result (pass/fail and a list of anomalies) | *Software Validation Report*  *Q5-29-028*  *9. Verification and Validation Documentation* | P |
|  | b) retain sufficient records to permit the test to be repeated | *Software Validation Report*  *Q5-29-028*  *9. Verification and Validation Documentation* | P |
|  | c) identify the tester | *Software Validation Report*  *Q5-29-028*  *9. Verification and Validation Documentation* | P |
| 5.8 | SOFTWARE RELEASE | |  |
| 5.8.1 | [B, C] The manufacturer ensured that software verification has been completed and the results evaluated before the software is released | *Software Validation Report*  *Q5-29-028*  *9. Verification and Validation Documentation* | P |
| 5.8.2 | [B, C] The manufacturer documented all known residual anomalies | *Software Validation Report*  *Q5-29-028*  *9. Verification and Validation Documentation* | P |
| 5.8.3 | [B, C] The manufacturer ensured that all known residual anomalies have been evaluated to ensure that they do not contribute to an unacceptable risk | *Software Validation Report*  *Q5-29-028*  *9. Verification and Validation Documentation* | P |
| 5.8.4 | [A, B, C] The manufacturer documented the version of the software product that is being released | *Software Validation Report*  *Q5-29-028*  *10. Revision Level History*  *12. Release Version Number* | P |
| 5.8.5 | [B, C] The manufacturer documented the procedure and environment used to create the released software | *Software Validation Report*  *Q5-29-028*  *8.1 Development Life Cycle* | P |
| 5.8.6 | [B, C] The manufacturer ensured that all activities and tasks are complete along with all the associated documentation | *Software Validation Report*  *Q5-29-028*  *8.1 Development Life Cycle* | P |
| 5.8.7 | [B, C] For at least a period of time determined as the longer of: the life time of the device as defined by the manufacturer or a time specified by relevant regulatory requirements, the manufacturer archived: | | P |
|  | a) the software product and configuration items | *Software Validation Report*  *Q5-29-028*  *8.3 Software Configuration Management Life Cycle* | P |
|  | b) the documentation | *Software Validation Report*  *Q5-29-028*  *8.3 Software Configuration Management Life Cycle* | P |
| 5.8.8 | [B, C] The manufacturer established procedures to ensure that the released software product can be reliably delivered to the point of use without corruption or unauthorised change | *Software Validation Report*  *Q5-29-028*  *10. Revision Level History* | P |
|  | These procedures addressed the production and handling of media containing the software product including as appropriate: | | P |
|  | – replication |  | N/A |
|  | – media labelling | *Software Validation Report*  *Q5-29-028*  *10. Revision Level History* | P |
|  | – packaging | *Software Validation Report*  *Q5-29-028*  *10. Revision Level History* | P |
|  | – protection | *Software Validation Report*  *Q5-29-028*  *10. Revision Level History* | P |
|  | – storage | *Software Validation Report*  *Q5-29-028*  *10. Revision Level History* | P |
|  | – delivery | *Software Validation Report*  *Q5-29-028*  *10. Revision Level History* | P |

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| **6** | **SOFTWARE MAINTENANCE PROCESS** | |  |
| 6.1 | [A, B, C] The manufacturer established a software maintenance plan (or plans) for conducting the activities and tasks of the maintenance process | *Software Validation Report*  *Q5-29-028*  *8.2 Software Maintenance Life Cycle* | P |
|  | The plan addressed the following: | |  |
|  | a) procedures for: | |  |
|  | – receiving | *Software Validation Report*  *Q5-29-028*  *8.2 Software Maintenance Life Cycle* | P |
|  | – documenting | *Software Validation Report*  *Q5-29-028*  *8.2 Software Maintenance Life Cycle* | P |
|  | – evaluating | *Software Validation Report*  *Q5-29-028*  *8.2 Software Maintenance Life Cycle* | P |
|  | – resolving | *Software Validation Report*  *Q5-29-028*  *8.2 Software Maintenance Life Cycle* | P |
|  | – tracking | *Software Validation Report*  *Q5-29-028*  *8.2 Software Maintenance Life Cycle* | P |
|  | feedback arising after release of the medical device software | |  |
|  | b) criteria for determining whether feedback is considered to be a problem | *Software Validation Report*  *Q5-29-028*  *8.2.1 Software Maintenance Life Cycle Procedure* | P |
|  | c) use of the software risk management process | *Software Validation Report*  *Q5-29-028*  *8.2.1 Software Maintenance Life Cycle Procedure* | P |
|  | d) use of the software problem resolution process for analysing and resolving problems arising after release of the medical device software | *Software Validation Report*  *Q5-29-028*  *8.2.1 Software Maintenance Life Cycle Procedure* | P |
|  | e) use of the software configuration management process (Clause 8) for managing modifications to the existing system | *Software Validation Report*  *Q5-29-028*  *8.2.1 Software Maintenance Life Cycle Procedure* | P |
|  | f) procedures to evaluate and implement, for soup: | | N/A |
|  | – upgrades | *Software Validation Report*  *Q5-29-028*  *10. Revision Level History* | N/A |
|  | – bug fixes | *Software Validation Report*  *Q5-29-028*  *11. Unsolved Bugs* | N/A |
|  | – patches | *Software Validation Report*  *Q5-29-028*  *10. Revision Level History* | N/A |
|  | – obsolescence | *Software Validation Report*  *Q5-29-028*  *10. Revision Level History* | N/A |
| 6.2 | PROBLEM AND MODIFICATION ANALYSIS | |  |
| 6.2.1 | DOCUMENT AND EVALUATE FEEDBACK | |  |
| 6.2.1.1 | [A, B, C] The manufacturer monitors feedback on released software product from both inside its own organization and from users | *Software Validation Report*  *Q5-29-028*  *8.2.2 Description of Software Maintenance Life Cycle Procedure* | P |
| 6.2.1.2 | [A, B, C] Feedback is documented and evaluated to determine whether a problem exists in a released software product. Any such problem is recorded as a problem report (see Clause 9) | *Software Validation Report*  *Q5-29-028*  *8.2.2 Description of Software Maintenance Life Cycle Procedure* | P |
|  | problem reports includes actual or potential adverse events, and deviations from specifications | *Software Validation Report*  *Q5-29-028*  *8.2.2 Description of Software Maintenance Life Cycle Procedure* | P |
| 6.2.1.3 | [A, B, C] Each problem report is evaluated to determine how it affects the safety of a released software product and whether a change to the released software product is needed to address the problem | *Software Validation Report*  *Q5-29-028*  *8.2.2 Description of Software Maintenance Life Cycle Procedure* | P |
| 6.2.2 | [A, B, C] The manufacturer uses the software problem resolution process (see Clause 9) to address problem reports | *Software Validation Report*  *Q5-29-028*  *8.2.2 Description of Software Maintenance Life Cycle Procedure* | P |
| 6.2.3 | [B, C] In addition to the analysis required by Clause 9, the manufacturer analyses each change request for its effect on the organization, released software products, and systems with which it interfaces | *Software Validation Report*  *Q5-29-028*  *8.2.2 Description of Software Maintenance Life Cycle Procedure* | P |
| 6.2.4 | [A, B, C] The manufacturer evaluates and approves change requests which modify released software products | *Software Validation Report*  *Q5-29-028*  *8.2.2 Description of Software Maintenance Life Cycle Procedure* | P |
| 6.2.5 | [A, B, C] The manufacturer identifies the approved change requests that affect released software products | *Software Validation Report*  *Q5-29-028*  *8.2.2 Description of Software Maintenance Life Cycle Procedure* | P |
|  | As required by local regulation, the manufacturer informed users and regulators about: | |  |
|  | a) any problem in released software products and the consequences of continued unchanged use | *Software Validation Report*  *Q5-29-028*  *8.2.2 Description of Software Maintenance Life Cycle Procedure* | P |
|  | b) the nature of any available changes to released software products and how to obtain and install the changes | *Software Validation Report*  *Q5-29-028(4*  *8.2.2 Description of Software Maintenance Life Cycle Procedure* | P |
| 6.3 | MODIFICATION IMPLEMENTATION | |  |
| 6.3.1 | [A, B, C] The manufacturer used the software development process (see Clause 5) or an established maintenance PROCESS to implement the modifications | *Software Validation Report*  *Q5-29-028*  *8.2.2 Description of Software Maintenance Life Cycle Procedure* | P |
| 6.3.2 | [A, B, C] The manufacturer released modified software systems according to 5.8. Modifications may be released as part of a full re-release of a software system or as a modification kit comprising changed software items and the necessary tools to install the changes as modifications to an existing software system. | *Software Validation Report*  *Q5-29-028*  *8.2.2 Description of Software Maintenance Life Cycle Procedure* | P |

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| **7** | **SOFTWARE RISK MANAGEMENT PROCESS** | |  |
| 7.1 | ANALYSIS OF SOFTWARE CONTRIBUTING TO HAZARDOUS SITUATIONS | |  |
| 7.1.1 | [B, C] The manufacturer identified software items that could contribute to a hazardous situation identified in the medical device risk analysis activity of ISO 14971 (see 4.2) | *Software Validation Report*  *Q5-29-028*  *3. RISK MANAGEMENT* | P |
| 7.1.2 | [B, C] The manufacturer identified potential causes of the software item identified above contributing to a hazardous situation | *Software Validation Report*  *Q5-29-028*  *3. RISK MANAGEMENT* | P |
|  | The manufacturer considered potential causes including, as appropriate: | *Software Validation Report*  *Q5-29-028*  *3. RISK MANAGEMENT* | P |
|  | a) incorrect or incomplete specification of functionality | *Software Validation Report*  *Q5-29-028*  *3. RISK MANAGEMENT* | P |
|  | b) software defects in the identified software item functionality | *Software Validation Report*  *Q5-29-028*  *3. RISK MANAGEMENT* | P |
|  | c) failure or unexpected results from soup | *Software Validation Report*  *Q5-29-028*  *3. RISK MANAGEMENT* | P |
|  | d) hardware failures or other software defects that could result in unpredictable software operation | *Software Validation Report*  *Q5-29-028*  *3. RISK MANAGEMENT* | P |
|  | e) reasonably foreseeable misuse | *Software Validation Report*  *Q5-29-028*  *3. RISK MANAGEMENT* | P |
| 7.1.3 | [B, C] If failure or unexpected results from soup is a potential cause of the software item contributing to a hazardous situation, the manufacturer evaluated as a minimum any anomaly list published by the supplier of the soup item relevant to the version of the soup item used in the medical device to determine if any of the known anomalies result in a sequence of events that could result in a hazardous situation | *Software Validation Report*  *Q5-29-028*  *1. Level of Concern* | P |
| 7.1.4 | [B, C] The manufacturer documented in the risk management file potential causes of the software item contributing to a hazardous situation (see ISO 14971) | *Software Validation Report*  *Q5-29-028*  *3. RISK MANAGEMENT* | P |
| 7.1.5 | [B, C] The manufacturer documented in the risk management file sequences of events that could result in a hazardous situation that are identified in 7.1.2 | *Software Validation Report*  *Q5-29-028*  *3. RISK MANAGEMENT* | P |
| 7.2 | RISK CONTROL MEASURES | |  |
| 7.2.1 | [B, C] For each potential cause of the software item contributing to a hazardous situation documented in the risk management file, the manufacturer defined and documented risk control measures | *Software Validation Report*  *Q5-29-028*  *3. RISK MANAGEMENT* | P |
| 7.2.2 | [B, C] If a risk control measure is implemented as part of the functions of a software item, the manufacturer: | |  |
|  | a) included the risk control measure in the software requirements | *Software Validation Report*  *Q5-29-028*  *3. RISK MANAGEMENT* | P |
|  | b) assigned a software safety class to the software item based on the possible effects of the hazard that the risk control measure is controlling | *Software Validation Report*  *Q5-29-028*  *3. RISK MANAGEMENT* | P |
|  | c) developed the software item in accordance with Clause 5 | *Software Validation Report*  *Q5-29-028*  *6. Software Design Specification(SDS)* | P |
| 7.3 | VERIFICATION OF RISK CONTROL MEASURES | |  |
| 7.3.1 | [B, C] The implementation of each risk control measure documented in 7.2 was verified, and this verification has been documented | *Software Validation Report*  *Q5-29-028*  *9. Verification and Validation Documentation* | P |
| 7.3.2 | [B, C] If a risk control measure is implemented as a software item, the manufacturer evaluated the risk control measure to identify and document in the risk management file any new sequences of events that could result in a hazardous situation | *Software Validation Report*  *Q5-29-028*  *3. RISK MANAGEMENT* | P |
| 7.3.3 | [B, C] The manufacturer documented traceability of software hazards as appropriate: | |  |
|  | a) from the hazardous situation to the software item | *Software Validation Report*  *Q5-29-028*  *7. Traceability* | P |
|  | b) from the software item to the specific software cause | *Software Validation Report*  *Q5-29-028*  *7. Traceability* | P |
|  | c) from the software cause to the risk control measure | *Software Validation Report*  *Q5-29-028*  *7. Traceability* | P |
|  | d) from the risk control measure to the verification of the risk control measure | *Software Validation Report*  *Q5-29-028*  *7. Traceability* | P |
| 7.4 | RISK MANAGEMENT OF SOFTWARE CHANGES | |  |
| 7.4.1 | [A, B, C] The manufacturer analysed changes to the medical device software (including soup) to determine whether: | |  |
|  | a) additional potential causes are introduced contributing to a hazardous situation | *Software Validation Report*  *Q5-29-028*  *3. RISK MANAGEMENT* | P |
|  | b) additional software risk control measures are required | *Software Validation Report*  *Q5-29-028*  *3. RISK MANAGEMENT* | P |
| 7.4.2 | [B, C] The manufacturer analysed changes to the software, including changes to SOUP, to determine whether the software modification could interfere with existing risk control measures | *Software Validation Report*  *Q5-29-028*  *3. RISK MANAGEMENT* | P |
| 7.4.3 | [B, C] The manufacturer performed relevant risk management activities defined in 7.1, 7.2 and 7.3 based on these analyses | *Software Validation Report*  *Q5-29-028*  *3. RISK MANAGEMENT* | P |

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| **8** | **SOFTWARE CONFIGURATION MANAGEMENT PROCESS** | |  |
| 8.1 | Configuration identification | |  |
| 8.1.1 | [A, B, C] The manufacturer established a scheme for the unique identification of configuration items and their versions to be controlled for the project. | *Software Validation Report*  *Q5-29-028*  *8.3.1 Software Configuration Management Life Cycle Procedure* | P |
|  | This scheme included other software products or entities such as soup and documentation. | *Software Validation Report*  *Q5-29-028*  *8.3.1 Software Configuration Management Life Cycle Procedure* | P |
| 8.1.2 | [A, B, C] For each soup configuration item being used, including standard libraries, the manufacturer documented: | | P |
|  | a) the title | *Software Validation Report*  *Q5-29-028*  *8.3 Software Configuration Management Life Cycle* | P |
|  | b) the manufacturer | *Software Validation Report*  *Q5-29-028*  *8.3 Software Configuration Management Life Cycle* | P |
|  | c) the unique soup designator | *Software Validation Report*  *Q5-29-028*  *8.3 Software Configuration Management Life Cycle* | P |
| 8.1.3 | [A, B, C] The manufacturer documented the set of configuration items and their versions that comprise the software system configuration | *Software Validation Report*  *Q5-29-028*  *8.3.1 Software Configuration Management Life Cycle Procedure* | P |
| 8.2 | CHANGE CONTROL | |  |
| 8.2.1 | [A, B, C] The manufacturer changed configuration items only in response to an approved change request | *Software Validation Report*  *Q5-29-028*  *8.3 Software Configuration Management Life Cycle* | P |
| 8.2.2 | [A, B, C] The manufacturer implemented the change as specified in the change request | *Software Validation Report*  *Q5-29-028*  *8.3 Software Configuration Management Life Cycle* | P |
|  | The manufacturer identified and performed any activity that needs to be repeated as a result of the change, including changes to the software safety classification of software systems and software items | *Software Validation Report*  *Q5-29-028*  *8.3 Software Configuration Management Life Cycle* | P |
| 8.2.3 | [A, B, C] The manufacturer verified the change, including repeating any verification that has been invalidated by the change and taking into account 5.7.3 and 9.7 | *Software Validation Report*  *Q5-29-028*  *8.3 Software Configuration Management Life Cycle* | P |
| 8.2.4 | [A, B, C] The manufacturer created an audit trail where can be traced each: | |  |
|  | a) change request | *Software Validation Report*  *Q5-29-028*  *7. Traceability* | P |
|  | b) relevant problem report | *Software Validation Report*  *Q5-29-028*  *7. Traceability* | P |
|  | c) approval of the change request | *Software Validation Report*  *Q5-29-028*  *7. Traceability* | P |
| 8.3 | [A, B, C] The manufacturer retains retrievable records of the history of controlled configuration items including system configuration | *Software Validation Report*  *Q5-29-028(4*  *8.3.1 Software Configuration Management Life Cycle Procedure* | P |

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| **9** | **SOFTWARE PROBLEM RESOLUTION PROCESS** | |  |
| 9.1 | [A, B, C] The manufacturer prepared a problem report for each problem detected in a software product. | *Software Validation Report*  *Q5-29-028*  *8.2.1 Software Maintenance Life Cycle Procedure* | P |
|  | problem reports were classified as follows: | |  |
|  | a) type | *Software Validation Report*  *Q5-29-028*  *8.2.1 Software Maintenance Life Cycle Procedure* | P |
|  | b) scope | *Software Validation Report*  *Q5-29-028*  *8.2.1 Software Maintenance Life Cycle Procedure* | P |
|  | c) criticality | *Software Validation Report*  *Q5-29-028*  *8.2.1 Software Maintenance Life Cycle Procedure* | P |
| 9.2 | [A, B, C] The manufacturer: | |  |
|  | a) investigated the problem and if possible identify the causes | *Software Validation Report*  *Q5-29-028*  *8.2.1 Software Maintenance Life Cycle Procedure* | P |
|  | b) evaluated the problem’s relevance to safety using the software risk management process (Clause 7) | *Software Validation Report*  *Q5-29-028*  *8.2.1 Software Maintenance Life Cycle Procedure* | P |
|  | c) documented the outcome of the investigation and evaluation | *Software Validation Report*  *Q5-29-028*  *8.2.1 Software Maintenance Life Cycle Procedure* | P |
|  | d) created a change request(s) for actions needed to correct the problem, or document the rationale for taking no action | *Software Validation Report*  *Q5-29-028*  *8.2.1 Software Maintenance Life Cycle Procedure* | P |
| 9.3 | [A, B, C] The manufacturer advised relevant parties of the existence of the problem, as appropriate | *Software Validation Report*  *Q5-29-028*  *8.2.2 Description of Software Maintenance Life Cycle Procedure* | P |
| 9.4 | [A, B, C] The manufacturer approved and implemented all change requests, observing the requirements of the change control process (see 8.2) | *Software Validation Report*  *Q5-29-028*  *8.2.2 Description of Software Maintenance Life Cycle Procedure* | P |
| 9.5 | [A, B, C] The manufacturer maintains records of problem reports and their resolution including their verification | *Software Validation Report*  *Q5-29-028*  *9. Verification and Validation Documentation* | P |
|  | The manufacturer updated the risk management file as appropriate (see 7.4) | *Software Validation Report*  *Q5-29-028*  *3. Risk Management* | P |
| 9.6 | [A, B, C] The manufacturer performed analysis to detect trends in problem reports | *Software Validation Report*  *Q5-29-028*  *8.2.1 Software Maintenance Life Cycle Procedure* | P |
| 9.7 | [A, B, C] The manufacturer verified resolutions to determine whether: | |  |
|  | a) problem has been resolved and the problem report has been closed | *Software Validation Report*  *Q5-29-028*  *8.2.1 Software Maintenance Life Cycle Procedure* | P |
|  | b) adverse trends have been reversed | *Software Validation Report*  *Q5-29-028*  *8.2.1 Software Maintenance Life Cycle Procedure* | P |
|  | c) change requests have been implemented in the appropriate software products and activities | *Software Validation Report*  *Q5-29-028*  *8.2.1 Software Maintenance Life Cycle Procedure* | P |
|  | d) additional problems have been introduced | *Software Validation Report*  *Q5-29-028*  *8.2.1 Software Maintenance Life Cycle Procedure* | P |
| 9.8 | [A, B, C] When testing, retesting or regression testing software items and systems following a change, the manufacturer included in the test documentation: | | P |
|  | a) test results | *Software Validation Report*  *Q5-29-028*  *8.3 Software Configuration Management Life Cycle* | P |
|  | b) anomalies found | *Software Validation Report*  *Q5-29-028*  *8.3 Software Configuration Management Life Cycle* | P |
|  | c) the version of software tested | *Software Validation Report*  *Q5-29-028*  *6. Software Design Specification*  *8.3 Software Configuration Management Life Cycle* | P |
|  | d) relevant hardware and software test configurations | *Software Validation Report*  *Q5-29-028*  *6. Software Design Specification*  *8.3 Software Configuration Management Life Cycle* | P |
|  | e) relevant test tools | *Software Validation Report*  *Q5-29-028*  *8.3 Software Configuration Management Life Cycle* | P |
|  | f) date tested | *Software Validation Report*  *Q5-29-028*  *8.3 Software Configuration Management Life Cycle* | P |
|  | g) identification of the tester | *Software Validation Report*  *Q5-29-028*  *8.3 Software Configuration Management Life Cycle* | P |

|  | **TABLE: Mapping of required evidence and manufacturer documents** | | | |  | |
| --- | --- | --- | --- | --- | --- | --- |
| Standard Clause | | Deliverables | Title | Revision # | Date |
| 4.2 | | Risk management file |  | 4 | 2015/05/28 |
| 4.3 | | Software safety classification document |  | 2 | 2015/03/05 |
| 5.1.1 | | Software development plan |  |  | 2015/03/05 |
| 5.1.3 | | Software requirements reference to software design and development document |  | 4 | 2015/05/28 |
| 5.1.4 | | Development standards, methods and tools records for class C software |  |  | 2015/03/05 |
| 5.1.5 | | Software integration and integration testing plan |  | 4 | 2015/05/28 |
| 5.1.6 | | Software verification plan |  | 4 | 2015/05/28 |
| 5.1.7 | | Software risk management plan |  | 4 | 2015/05/28 |
| 5.1.8 | | Document management procedures |  | 2 | 2015/03/05 |
| 5.1.9 | | Software configuration management procedures |  | 2 | 2015/03/05 |
| 5.2 | | Software system requirements specification |  | 4 | 2015/05/28 |
| 5.3 | | Software system architecture design specification |  | 2 | 2015/03/05 |
| 5.3 | | Software item architecture design specification |  | 2 | 2015/03/05 |
| 5.4 | | Software item detailed design specification |  | 2 | 2015/03/05 |
| 5.4 | | Software unit detailed design specification |  | 2 | 2015/03/05 |
| 5.5.1 | | Software unit implementation records |  | 4 | 2015/05/28 |
| 5.5.2 | | Software unit verification process |  | 4 | 2015/05/28 |
| 5.5.3 | | Software unit acceptance criteria |  | 4 | 2015/05/28 |
| 5.5.5 | | Software unit verification records |  | 4 | 2015/05/28 |
| 5.6.1 | | Software unit integration process |  | 4 | 2015/05/28 |
| 5.6.2 | | Software unit integration records |  | 4 | 2015/05/28 |
| 5.6.4 | | Software unit integration testing records |  | 4 | 2015/05/28 |
| 5.6.5 | | Evaluation of software unit integration test |  | 4 | 2015/05/28 |
| 5.6.6 | | Software unit regression testing process |  | 4 | 2015/05/28 |
| 5.6.7 | | Software unit regression testing records |  | 4 | 2015/05/28 |
| 5.6.8 | | Software problem resolution process |  | 4 | 2015/05/28 |
| 5.7 | | Software system testing process |  | 4 | 2015/05/28 |
| 5.8 | | Software system release process |  | 4 | 2015/05/28 |
| 6.1 | | Software maintenance plan |  | 4 | 2015/05/28 |
| 6.2.1 | | Software document and evaluate feedback process |  | 4 | 2015/05/28 |
| 6.2.1 | | Software problem reports |  | 4 | 2015/05/28 |
| 6.2.2 | | Software problem resolution process addressed to problem reports |  | 4 | 2015/05/28 |
| 6.2.3 | | Change requests process |  | 4 | 2015/05/28 |
| 6.2.5 | | Communication to user and regulators process |  | 4 | 2015/05/28 |
| 7.1 | | Software hazard analysis process |  | 4 | 2015/05/28 |
| 7.1 | | SOUP anomaly lists |  | 4 | 2015/05/28 |
| 7.2 | | Risk control process |  | 4 | 2015/05/28 |
| 7.3 | | Risk control verification process |  | 4 | 2015/05/28 |
| 7.4 | | Risk management of software change process |  | 4 | 2015/05/28 |
| 8.1 | | Configuration identification record |  | 4 | 2015/05/28 |
| 8.2 | | Change control process |  | 2 | 2015/03/05 |
| 9 | | Software problem resolution process |  | 4 | 2015/05/28 |
| **Supplementary information: None** | | | | | | |