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| **INSTRUCTIONS** |
| **Important: Please read and follow these instructions carefully:**   * All documentation must be in English. * **Before you begin, please ensure the accompanying ‘MDR Technical Questionnaire Data Folder’ is ready.** * Data and supporting documents must be uploaded using this Data Folder set, where each question has a corresponding Folder. * When the same document is used to support more than one question it **must** be uploaded to **each** relevant Folder. * Supporting documents must be provided in a **searchable** format. * Please complete all relevant sections of the form. Tick the NA box in the header for all non-relevant sections. * NSAI is aware that certain questions within this form appear to overlap with elements of the MDR Product Review forms. Please note this is deliberate, but the focus of this questionnaire is on the **Quality System** processes which are being implemented. This differs from the focus of the MDR Product Review form where similar questions/data may have been requested. **Regardless of this,** answer all relevant questions on this form. * **When providing supporting documentation clearly indicate/highlight all relevant parts that address the specific question.**  |  | | --- | | **The review will not begin until data is received in this format. Repeat failure will result in cancellation of the review.** |   All forms and supporting data can only be submitted via the NSAI upload facility: <https://www.nsaiinc.com/upload/qms/>  For any queries on how to complete this form please contact: [medical.devices@nsai.ie](mailto:medical.devices@nsai.ie) |

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| **GENERAL INFORMATION:** | | | | | | | | | | |
| Company Name: |  | | | | | | | | | |
| Address: |  | | | | | | | | | |
| Management Representative: |  | | | | | | | | | |
| Contact Name (if different)[[1]](#footnote-1): |  | | | | | | | | | |
| E-mail Address: |  | | | | | Telephone No.: | |  | | |
| MDR Classification | Class Is | | Class Ir | Class Im | | Class IIa | Class IIb  Non-Implant. | | Class IIb Implant. | Class III |
|  | |  |  | |  |  | |  |  |
| Conformity Assessment Route |  | ANNEX IX | | |  | ANNEX XI (Part A) | |  | ANNEX XVI | |

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| **SITE INFORMATION (relevant to this application):** | | | |
|  | Single Site |  | Multiple Locations as listed beneath |
| |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | Contact Details and Products for each site covered under QMS, and also their associated QMS activities. | | | Management / Admin. | Regulatory Affairs | Sterilisation Site | Design / development | Production / Assembly | Final QC / testing / Release | Other. (Please provide details) | | Company/Division/Business Unit: | Contact: | |  |  |  |  |  |  |  | | Address: | Email: | Tel: | | Headcount:  Products: | | | Company/Division/Business Unit: | Contact: | |  |  |  |  |  |  |  | | Address: | Email: | Tel: | | Headcount:  Products: | | | Company/Division/Business Unit: | Contact: | |  |  |  |  |  |  |  | | Address: | Email: | Tel: | | Headcount:  Products: | | | Company/Division/Business Unit: | Contact: | |  |  |  |  |  |  |  | | Address: | Email: | Tel: | | Headcount:  Products: | | | Company/Division/Business Unit: | Contact: | |  |  |  |  |  |  |  | | Address: | Email: | Tel: | | Headcount:  Products: | | | | | |
| |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Products**  **and their Indications for Use** | **MDD/MDR File Number:**  **25X.XXX.XX**  **745.XXX.XX**  **NA** | **Non-Active Device** | **Active Device** | **Tissues of Animal Origin** | **Medicinal Substances** | **Sterilisation Method** | | | | | | Moist Heat (MH) | Irradiation (R) | Ethylene Oxide (EtO) | Chemical (C) | Aseptic (A) | |  |  |  |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |  |  |  | | ***Add additional rows if required*** |  |  |  |  |  |  |  |  |  |  | | | | |

| **Before you begin:**   * Please provide as much detail as possible in the Client response and supporting evidence box for all questions, including specific references to additional documents. * In the left-hand side “Q column”, under the Question Number, the ‘S1’ (shaded questions) and ‘S2’ identifiers under each question number are for internal NSAI use only. * All applicable sections and questions within must be completed in full. * This form will be used as part of the Stage 1 and Stage 2 assessment. |
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| **Q** | **ANNEX I**  **GENERAL SAFETY AND PERFORMANCE REQUIREMENTS** | | | |
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| **Note:** The ‘S1’ and ‘S2’ identifiers for each question number are for internal NSAI use only. All relevant questions must be fully addressed. | | | |
| **EN ISO:**  **13485**  **:2016 / Directive** | **MDR Requirement** | **Client Response and supporting evidence** | |
| ***CHAPTER I, GENERAL REQUIREMENTS*** | | | | |
| **1**  **S1** | 4.1, 7.1,  7.2.1 c), 7.2.2 c), 7.3, 7.5  4.1.2  8.2.1  7.2.1b), d),  7.2.2d),  7.3.4d)  7.2.1b),  7.2.2d), 7.3.3  MDD 93/42/EEC  Annex I | **Chapter I Section 1 – 5**  **Risk Requirements under MDR.**  Explain how Risk Management is applied to address the requirements of ANNEX I Chapter I, Sections 1 – 5; for example, but not limited to Product Realization including design and user requirements.  Supporting documents shall be uploaded to the **Q1 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document**.  Examples of supporting documents for this question include e.g. GSPR Checklist and GSPR SOP, Relevant SOPs for Risk Documents, etc. | Client Response… | |
| Q1 Auditor Review: | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| **2**  **S2** | 4.2.4, 4.2.5,  7.2.1, 7.3.6,  7.3.7, 7.5.11  4.2.3c),  7.5.11 | **Chapter I Section 6 – 7**  **Performance Characteristics over the Lifetime of Device.**  How are the performance characteristics over the lifetime of the medical device(s) in relation to the requirements of Chapter I Section 6 – 7 met?  Supporting documents shall be uploaded to the **Q2 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document**  Examples of supporting documents for this question may include e.g. Relevant SOP(s) for shelf life (including packaging and functional testing), transport, storage | Client Response… | |
| Q2 Auditor Review: | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |

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| ***CHAPTER II, REQUIREMENTS REGARDING DESIGN AND MANUFACTURE*** | | | | | | |
| **3**  **S2** | 4.1.1, 4.1.2 b), 4.1.3 e), 4.1.4    Annex I, 7.2., 7.5. | **Chapter II Section 10.4 Substances**  Please confirm if any substances which are **carcinogenic, mutagenic or toxic to reproduction (‘CMR’**) or substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health are used?  LINK TO SCHEER Guidance Document on benefit risk analysis.  <https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_o_015.pdf>  Supporting documents shall be uploaded to the **Q3 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. Benefit/Risk Analysis, and any relevant SOPS etc. |  | | Confirm question is not applicable, provide a justification below. | |
| Client Response… | | | |
| Q3 Auditor Review: | | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| **4**  **S2** | 0.1, 4.1.2 b), 4.2.3, 7.6  Annex I, 9.1., 9.2., 9.3., 10.2., 13.6. (n) | **Chapter II Section 14 Construction of Devices and Interaction with their environment**  **If relevant,** please demonstrate how Risk Management is applied to address the new requirements of ANNEX I Chapter II Section 14?  For example, but not limited to:  14.1 Connections/Misconnection/Gas Transfer, etc.  14.2 Electromagnetic effects/Radiation  14.7 Safe disposal after use  Supporting documents shall be uploaded to the **Q4 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. Relevant SOPS for Specification / Verification and Validation documents, testing protocols etc. | Client Response… | | | |
| Q4 Auditor Review: | | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| **5**  **S2** | Annex I, 10.1, 10.3. | **Chapter II Section 15 Devices with a diagnostic or measuring function**  **If relevant**, please demonstrate how the new MDR requirements for *'precision accuracy and stability*’ for *'diagnostic devices*' are addressed.  Supporting documents shall be uploaded to the **Q5 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. Relevant SOP(s) for V&V, Stability, Design / Product Specification, etc. | Client Response… | | | |
| Q5 Auditor Review: | | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| **6**  **S2** | 4.1.6  Annex I, 12.1. | **Chapter II Section 17 Electronic programmable systems**  **If relevant,** please demonstrate how the new MDR requirements for Section 17 have been addressed?  For example, but not limited to:   * SaMD (software as a Medical device); * Cyber Risk; * Combination with mobile platforms.   Supporting documents shall be uploaded to the **Q6 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. SaMD in RM and relevant SOP(s), Design / Product Specification SOP, etc. | Client Response… | | | |
| Q6 Auditor Review: | | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| **7**  **S2** |  | **Chapter II Section 22 Protection against the risks posed by medical devices intended by the manufacturer for** **use by lay persons**  **If relevant,** please demonstrate how the new MDR requirements for Section 22 have been addressed via Risk Management processes and/or usability?  Supporting documents shall be uploaded to the **Q7 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. Relevant SOP(s) for RM documents, Design / Product Specifications, Design V&V including IEC 60601 series, Software V&V, Physical, Functional testing, IFU and Usability, etc. |  | Confirm question is not applicable, provide a justification below. | | |
| Client Response… | | | |
| Q7 Auditor Review: | | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |

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| ***CHAPTER III, REQUIREMENTS REGARDING THE INFORMATION SUPPLIED WITH THE DEVICE*** | | | |
| **8**  **S2** |  | **Chapter III Section 23. Label and Instructions for Use**  Please demonstrate how the new MDR requirements for Labels and IFU (Section 23) have been addressed?  Please ensure Annex II Section 2 requirements relating to labels and IFU in other languages are addressed.  Please provide a link(s) to the most current version of the website(s).  Supporting documents shall be uploaded to the **Q8 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. Relevant SOPs for Label control / IFU and SOP for IFU control / website/electronic IFU if appropriate, IFU and label translation SOP, draft set of labels in English etc.  **Note: If relevant, please include details for CMR’s and/or endocrine-disrupting substances [Chapter II, 10.4.1., 10.4.5 and ANNEX II, 6.2 (d)]**  If relevant, please provide the SOP / reference(s) describing how substances which are carcinogenic, mutagenic or toxic to reproduction (‘CMR’) are addressed in device labelling (device labels and/or IFU). | Client Response… |

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|  | Q8 Auditor Review: | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |

|  | **ANNEX IX**  **CONFORMITY ASSESSMENT BASED ON A Qms AND ON ASSESSMENT OF TECHNICAL DOCUMENTATION**  ***Only complete if planning to submit a Product Review under ANNEX IX conformity assessment route*** | | | | | ***Tick if Not applicable*** |
| --- | --- | --- | --- | --- | --- | --- |
| **EN ISO:**  **13485**  **:2016 / Directive** | **MDR Requirement** | **Client Response and supporting evidence** | | | |
| ***CHAPTER I, QUALITY MANAGEMENT SYSTEM*** | | | | | | |
| **9**  **S1** | 1, 4.1  Annex II, 1. | **Chapter I. Section 1**  Provide Quality Manual, Process Clause Matrix (or equivalent) and/or explain how the Quality Management System (QMS) is established, documented and implemented and maintained effective throughout all phases of the device life cycle.  Supporting documents shall be uploaded to the **Q9 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question include Quality Manual, Quality Policy Quality Documents, Process Clause Matrix (or equivalent), etc. | Client Response… | | | |
| Q9 Auditor Review: | | | | Stage 1:  **Verified: Y/N** | |
| Stage 2:  **Verified: Y/N** | |
| **10**  **S1** | 4.1.1,  4.1.2,  4.2.3a),  7.1,  7.2.1c),  7.2.3,  7.3.3,  7.3.7,  7.3.9,  7.5.1e)  Annex II, 3.2. | **ANNEX IX Chapter I. Section 2 and Chapter 2 Article 11 Section 3**  **2.2 b)**  Does the company use an Authorised Representative (AR)?  If so, provide details.  Supporting documents shall be uploaded to the **Q10 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. Authorised Representative; ensure there is a valid letter of appointment or Agreement in place, and Job Description or CV (if EU rep is individual), etc. |  | Confirm AR is not applicable, provide a justification below. | | |
| Client Response… | | | |
| Q10 Auditor Review: | | | | Stage 1:  **Verified: Y/N** | |
| Stage 2:  **Verified: Y/N** | |
| **11**  **S1** | 4.1.1,  4.1.2,  4.2.3a)  7.1,  7.2.1c)  7.2.3,  7.3.3,  7.3.7,  7.3.9,  7.5.1e)  Annex II, 3.2. | **ANNEX IX Chapter I 2.2 (c-e) [including ANNEX II, 3]**  Please demonstrate that there is a documented strategy for regulatory compliance in place; covering relevant legal requirements, qualification, classification, equivalence, conformity assessment procedures, identification of applicable GSPR’s, risk management, clinical evaluation and the technical documentation.  Please demonstrate how management of design or quality management system changes are addressed in your QMS. In order to support this, please supply evidence to compliance with ANNEX II Section 3 Design and Manufacturing Information – with specific reference to complete information and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing for the product(s) which are under evaluation by NSAI    Supporting documents shall be uploaded to the **Q11 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. Manufacturing process validations, Design Change Procedure, other relevant change procedures, etc. | Client Response… | | | |
|  | **ANNEX IX Section 6 Batch Verification**  In the case of devices incorporating, as an integral part, a medicinal substance which, if used separately, would be considered to be an integral part of the device; please provide evidence of Batch History/Record control.  Supporting documents shall be uploaded to the **Q11 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. BHR SOP(s), NB Communication procedure, etc. | Client Response… | | | |
| Q11 Auditor Review: | | | | Stage 1:  **Verified: Y/N** | |
| Stage 2:  **Verified: Y/N** | |
| **12**  **S1** | 4,1,4, 7.2.3  Annex II, 3.4. | **ANNEX IX Chapter I 2.4**  Please provide evidence that QMS has taken into consideration that the manufacturer in question shall inform the notified body which approved the quality management system of any plan for substantial changes to the quality management system, or the device-range covered.  Supporting documents shall be uploaded to the **Q12 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. Change Control SOP(s), QMS / Product change SOP etc. | Client Response… | | | |
| Q12 Auditor Review: | | | | Stage 1:  **Verified: Y/N** | |
| Stage 2:  **Verified: Y/N** | |
| ***Chapter III ADMINISTRATIVE PROVISIONS*** | | | | | | |
| **13**  **S1** | 4.2.5  Annex II, 6. | **ANNEX IX Chapter III. 7-8**  Please provide evidence that QMS has taken into consideration that the manufacturer or, where the manufacturer does not have a registered place of business in a Member State, its authorised representative shall, for a period ending no sooner than 10 years, and in the case of implantable devices no sooner than 15 years, after the last device has been placed on the market retain relevant documentation, including documentation requirements in case a manufacturer or its authorised representative goes bankrupt or ceases business activity.  Supporting documents shall be uploaded to the **Q13 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. **Document Retention SOP, etc.** | Client Response… | | | |
| Q13 Auditor Review: | | | | Stage 1:  **Verified: Y/N** | |
| Stage 2:  **Verified: Y/N** | |

|  | **ANNEX XI – Part A**  **CONFORMITY ASSESSMENT BASED ON PRODUCT CONFORMITY VERIFICATION**  ***Only complete if planning to submit a Product Review under ANNEX XI conformity assessment route*** | | | | ***Tick if Not applicable*** |
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| **EN ISO:**  **13485**  **:2016 / Directive** | **MDR Requirement** | **Client Response and supporting evidence** | | |
| ***Part A – Section 6 Quality Management System*** | | | | | |
| 14  S1 | 4.1  Annex V, 3.2 | **ANNEX XI Part A 6.2**  Please provide Quality Manual, any other relevant SOPs **(with the specific sections clearly indicated/highlighted)**, and/or explain how the Quality Management System (QMS) is established, documented, implemented and maintained effective throughout the life cycle of the devices  Supporting documents shall be uploaded to the **Q14 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question include Quality Manual, Quality Policy Quality Documents, Process Clause Matrix (or equivalent), etc. | Client Response… | | |
| Q14 Auditor Review: | | | Stage 1:  **Verified: Y/N** | |
| Stage 2:  **Verified: Y/N** | |
| 15  S1 |  | **ANNEX XI Part A 6.~~4~~**  Please provide evidence that QMS has taken into consideration that the manufacturer in question shall inform the notified body which approved the quality management system of any plan for substantial changes to the quality management system, or the device-range covered.  Supporting documents shall be uploaded to the **Q15 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. QMS / Product Change Procedure, SOP for control of substantial changes to the quality management system, or the device-range covered, etc. | Client Response… | | |
| Q15 Auditor Review: | | | Stage 1:  **Verified: Y/N** | |
| Stage 2:  **Verified: Y/N** | |
| 16  S2 | 4.2.3 | **ANNEX XI Part A 8 Batch Verification**  In the case of devices incorporating, as an integral part, a medicinal substance which, if used separately, would be considered to be an integral part of the device; please provide evidence of Batch History/Record control.    Supporting documents shall be uploaded to the **Q17 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. BHR SOP(s), NB Communication procedure, etc. | Client Response… | | |
| Q16 Auditor Review: | | | Stage 1:  **Verified: Y/N** | |
| Stage 2:  **Verified: Y/N** | |
| 17  S1 | Various,  Annex V, 5.1. | **ANNEX XI Chapter Part A 10.5**  Does the company use an Authorised Representative?  Supporting documents shall be uploaded to the **Q17 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. for Authorised Representative; ensure there is a valid letter of appointment or Agreement in place, job description, CV, etc. | Client Response… | | |
| Q17 Auditor Review: | | | Stage 1:  **Verified: Y/N** | |
| Stage 2:  **Verified: Y/N** | |

|  | **ANNEX II**  **TECHNICAL DOCUMENTATION** | | | |
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| **EN ISO:**  **13485**  **:2016 / Directive** | **MDR Requirement** | **Client Response and supporting evidence** | |
| ***CHAPTER I, DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES*** | | | | |
| 18  S2 | 4.2.3  MDD Annex II, 3.2 (c) | **ANNEX II Chapter I Section 1.1**  Please provide details of the Device Description and Specifications and the technical summary thereof, if applicable to be drawn up by the manufacturer and presented in a clear, organised, readily searchable and unambiguous manner.  Supporting documents shall be uploaded to the **Q18 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. Technical File/ Design Dossier maintenance SOP or equivalent, associated SOPs, etc. | Client Response… | |
| Q18 Auditor Review: | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |

|  | **ANNEX IV**  **EU DECLARATION OF CONFORMITY (Including Article 19)** | | | |
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| **EN ISO:**  **13485**  **:2016 / Directive** | **MDR Requirement** | **Client Response and supporting evidence** | |
| 19  S2 |  | **ANNEX IV - EU Declaration of Conformity**  Please provide the SOP outlining how the EU Declaration(s) of Conformity (DoC) is generated, controlled and maintained, including procedures relating to language translation as required.  Please provide the proposed template for the EU Declaration(s) of Conformity. Please provide a copy of the product verification SOP(s).  Supporting documents shall be uploaded to the **Q19 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. DoC maintenance SOPs, Draft of DOC Template, etc. | Client Response… | |
| Q19 Auditor Review: | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 20  S2 |  | **Chapter 2 Article 19 Declaration of Conformity**  If applicable, have other Union legislations (e.g. REACH, RoHS, WEEE, etc.) been incorporated into the current DoC’s as per Article, 19.2?  Supporting documents shall be uploaded to the **Q20 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g.DoC SOP(s), Draft of DOC, etc. | Client Response… | |
| Q20 Auditor Review: | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |

|  | **ANNEX VI**  **INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLES 29(4) AND 31, CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE TOGETHER WITH THE UDI-DI IN ACCORDANCE WITH ARTICLES 28 AND 29, AND THE UDI SYSTEM** | | | | |
| --- | --- | --- | --- | --- | --- |
| **EN ISO:**  **13485**  **:2016 / Directive** | **MDR Requirement** | | **Client Response and supporting evidence** | |
| ***PART A: INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF DEVICES*** | | | | | |
| 21  S1 | N/A | | N/A  **ANNEX VI PART A – 1.1-1.4**  Please provide details of SOP which covers the registration in EUDAMED of Economic Operators (EO) i.e., Authorised Representative, Importer, Distributor and PRRC.  Supporting documents shall be uploaded to the **Q21 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g., EUDAMED SOPs and / or evidence of engagement and registration with your local Competent Authority.  Please refer to MDCG 2020-15 (*MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States*) for additional details on this matter.  https://ec.europa.eu/health/sites/health/files/md\_sector/docs/2020-15-position-paper-actor-registration-module\_en.pdf | Client Response… | |
| Q21 Auditor Review: | | | | Stage 1:  **Verified: Y/N** | |
| Stage 2:  **Verified: Y/N** | |
| 22  S1 | N/A | | **ANNEX VI PART A – 2.1-2.15 UDI-DI**  Please provide details of SOP in place to handle the Basic UDI-DI requirements, including but not limited to UDI-DI creation and application, UDI-DI maintenance and overall controls for the UDI process.  Supporting documents shall be uploaded to the **Q22 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g.UDI specific SOPs, SOP for Labelling control. | Client Response… | |
| Q22 Auditor Review: | | | | Stage 1:  **Verified: Y/N** | |
| Stage 2:  **Verified: Y/N** | |

|  | **CHAPTER 2**  **MAKING AVAILABLE ON THE MARKET AND PUTTING INTO SERVICE OF DEVICES, OBLIGATIONS OF ECONOMIC OPERATORS, REPROCESSING, CE MARKING, FREE MOVEMENT** | | | | |
| --- | --- | --- | --- | --- | --- |
| **EN ISO:**  **13485**  **:2016 / Directive** | | **MDR Requirement** | **Client Response and supporting evidence** | |
| 23  S2 |  | **Chapter 2 Article 7: Claims**  Please provide details specifically in relation to advertising (including website) to show evidence of compliance to the requirements of Chapter 2 Article 7.  Supporting documents shall be uploaded to the **Q23 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. Advertising policy, On-line Activities Procedure, Change Control or Document Control SOP, etc. | | Client Response… | |
| Q23 Auditor Review: | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 24  S1 |  | **Chapter 2 Article 9: Common Specifications (CS).**  Where relevant, please provide evidence of how new Common Specifications are incorporated into system processes. Please provide evidence of how changes to current Common Specifications or the publication of new Common Specifications are monitored.  Supporting documents shall be uploaded to the **Q24 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. Design / Manufacturing SOP(s), etc. | | Company Response… | |
| Q24 Auditor Review: | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 25  S1 |  | **Chapter 2 Article 10, General obligations of manufacturers**  **Section 15**  Please provide evidence of agreement/document between legal manufacturer and other legal entity responsible for design or manufacturer allowing information to be provided to EUDAMED.  Supporting documents shall be uploaded to the **Q25 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. EUDAMED Registration, EUDAMED update SOP(s), etc. | | Company Response… | |
| Q25 Auditor Review: | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 26  S2 |  | **Chapter II Article 10, Section 16**  Please provide evidence of insurance policy which includes cover for product liability claims.  Supporting documents shall be uploaded to the **Q26 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g.Insurance policy number/documents or similar. | | Company Response… | |
| Q26 Auditor Review: | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 27  S2 |  | **Chapter 2 Article 13 General Obligations of importers.**  If relevant, please provide evidence (agreement and/or SOP) outlining the process/responsibilities of the importer.  Supporting documents shall be uploaded to the **Q27 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. Importer specific agreements, SOPs. | | Yes  No | Confirm if Importer requirements are applicable |
| Company Response… | |
| Q27 Auditor Review: | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 28  S2 |  | **Chapter 2 Article 14 General Obligations of Distributors.**  Please provide evidence (agreement and/or SOP) outlining the process/responsibilities of distributor.  Supporting documents shall be uploaded to the **Q28 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. Distributor specific agreements/responsibilities, SOPs. | | Yes  No | Confirm if distributor requirements are applicable |
| Company Response… | |
| Q28 Auditor Review: | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 29  S1 |  | **Chapter 2 Article 15. Person responsible for regulatory compliance**  Please indicate who is the PRRC and provide evidence of how they meet compliance to **Article 15.1 a and/or b.**  **If instead, you are claiming compliance to Article 15.2 please provide evidence to support this (Micro and small enterprises).**  Supporting documents shall be uploaded to the **Q29 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. SOP(s) on PRRC responsibilities, Job Description(s), CV(s) for person(s), etc. | | Company Response… | |
| Q29 Auditor Review: | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 30  S2 |  | **Chapter 2 Article 17 Single-use devices and their reprocessing**  If relevant, please indicate if you reprocess single use devices.  If relevant, please indicate in which European jurisdictions Single-use devices are being placed on the market.  Please provide evidence from the relevant CA that the placing of reprocessed single use devices is permitted to under national law.  If relevant, please provide the list of any CS/HS or national provisions used. Please provide the SOP to ensure maintenance and update of CS/HS or national provisions used.  Supporting documents shall be uploaded to the **Q30 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. National Competent Authority decision on reprocessing in all member states where product is intended to be sold, CS/HS SOPs. | | Company Response… | |
| Q30 Auditor Review: | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 31  S2 |  | **Implantable Devices only**  **Chapter 2 Article 18 Implant Card and information to be supplied to the patient with an implanted device.**  If relevant, please provide evidence to demonstrate compliance to the requirements for Implant cards and patient information as per Article 18.  Supporting documents shall be uploaded to the **Q31 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g.Relevant Documentation/ potentially IFU SOP(s), Implant Card SOP(s), a copy (or draft) of the Implant Card, etc. | | Company Response… | |
| Q31 Auditor Review: | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 32  S2 |  | **Chapter 2 Article 23 Parts and components**  If relevant, please provide service or other SOPs which allow the repair of parts of the device without affecting safety and performance characteristics or the intended use.  Supporting documents shall be uploaded to the **Q32 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. Repair SOP(s), Servicing SOP(s), etc. | | Company Response… | |
| Q32 Auditor Review: | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |

|  | **POST-MARKET SURVEILLANCE AND VIGILANCE INCLUDING RELATED TECHNICAL DOCUMENTATION**  **ANNEX III TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE**  **CHAPTER VII POST-MARKET SURVEILLANCE AND VIGILANCE** | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **EN ISO 13485**  **:2016** | **MDD 93/42/ EEC,**  **AIMD**  **90/385/EEC,**  **MEDDEV’s** | MDR Requirement | Response/Evidence | | Auditor verification  For office use only |
| ***ANNEX III: TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE*** | | | | | | |
| 33  S2 | **MDD** Annex X 1.1(c) | Please provide evidence of the on post-market surveillance system in place to show compliance with **Chapter VII Articles 83 to 84 and ANNEX III section 1.1.**  Supporting documents shall be uploaded to the **Q33 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. SOPs on PMS System, all relevant SOPs for PMS Plan, etc… | | Company Response… | | |
| Q33 Auditor Review: | | | | Stage 1:  **Verified: Y/N** | |
| Stage 2:  **Verified: Y/N** | |
| 34  S2 |  | Please provide evidence of the Periodic Safety Update Report (PSUR) in place to show compliance with **Chapter VII Article 86 and ANNEX III 1.2**.  Supporting documents shall be uploaded to the **Q34 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. SOP on PSUR, PSUR if available, EUDAMED SOP for transmission of PSUR to NB if applicable, etc… | | Company Response… | | |
| Q34 Auditor Review: | | | | Stage 1:  **Verified: Y/N** | |
| Stage 2:  **Verified: Y/N** | |
| 35  S2 |  | **Chapter VII Articles 87-89**  Please provide evidence on the Vigilance reporting system in place to show compliance with Articles 87-89 and already in place current MED DEV 2.12 requirements.  Please provide a copy of:  a) Customer complaint and feedback procedure  b) a list of complaints opened or closed since the last audit.  Supporting documents shall be uploaded to the **Q35 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. SOP for reporting of events, complaint handling, decision trees, vigilance reporting procedure, incident trending and analysis of incidents/events, EUDAMED SOP for reporting, etc. | | Company Response… | | |
| Q35 Auditor Review: | | | | Stage 1:  **Verified: Y/N** | |
| Stage 2:  **Verified: Y/N** | |

|  | ***CLINICAL REQUIREMENTS***  ***Chapter VI Clinical Evaluation and Investigation***  ***ANNEX XIV CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP***  ***ANNEX XV CLINICAL INVESTIGATION*** | | | | |
| --- | --- | --- | --- | --- | --- |
| **EN ISO 13485**  **:2016** | **MDD 93/42/ EEC,**  **AIMD**  **90/385/EEC,**  **MEDDEV’s** | **MDR Requirement** | **Response/Evidence** | |
| ***CLINICAL EVALUATION REPORT (CER)*** | | | | | |
| 36  S1 |  | **Chapter 6 Article 61 (Applicable to all devices)**  Please provide a copy of the relevant Clinical Evaluation SOP(s) including all Risk Management (RM), PMS and Post Market Clinical Follow-up (PMCF) SOPs with the relevant sections indicated/highlighted to demonstrate the following:  Critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device, where the following conditions (a-c) are satisfied:  (a) It is demonstrated that the device subject to clinical evaluation for the intended purpose is equivalent to the device to which the data relate, in accordance with Section 3 of Annex XIV, and  The data adequately demonstrate compliance with the relevant general safety and performance requirements;  (b) a critical evaluation of the results of all available clinical investigations, taking duly into consideration whether the investigations were performed under Articles 62 to 80, any acts adopted pursuant to Article 81, and Annex XV; and  (c) a consideration of currently available alternative treatment options for that purpose, if any.   * If relevant, please provide evidence to justify the requirements of ANNEX XIV Part A in relation to **equivalence** are being met.   Supporting documents shall be uploaded to the **Q36 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. Clinical Evaluation SOP(s) including all RM, PMS and PMCF SOPs, Literature search evaluations, Equivalence documentation/reports, SOP for CER maintenance/update, a copy of the CER (draft), etc. | | Company Response… | |
|  | Q36 Auditor Review: | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 37  S1 |  | **Chapter 6 Art 61.2 (Class III implantable devices and class IIb active devices as per Article 54 1(b) – Expert Panel)**  Please provide a copy of the relevant Clinical Evaluation SOP(s) with the relevant sections indicated/highlighted to demonstrate the following:  If applicable: please provide all previous correspondence with Expert Panels to date.  **[For class III devices and class IIb active]** devices intended to administer/remove medicinal products] Decide whether to take up option to consult expert panel prior to clinical evaluation/investigation (Article 106) to review strategy/proposal. Shall give due consideration to views of panel, to be documented in clinical evaluation report, but may not invoke rights to panel's views for future assessments.  Supporting documents shall be uploaded to the **Q37 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. Clinical Evaluation SOP(s) Communication with Expert Panel SOP, SOP for CER maintenance/update, a copy of the CER (draft), etc. | | Company Response… | |
|  | Q37 Auditor Review: | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 38  S1 |  | **Chapter 6 Art 61.4, 5 (Clinical Equivalence for Class III and implantable devices)**  Please provide a copy of the relevant Clinical Evaluation SOP(s) and PMCF Plan and report if available (or interim report) with the relevant sections indicated/highlighted to demonstrate the following:  Assess whether evidence requirements can be satisfied in virtue of equivalence with existing device already on market, the clinical investigations of which are sufficient to demonstrate conformity. If yes, obtain Notified Body's endorsement of demonstration of equivalence, put into place clear contract with manufacturer of marketed device (where different) guaranteeing full and permanent access to technical documentation, provide evidence that original investigations were conducted in line with MDR requirements and description of nature of modification. If no, conduct clinical investigation.  Supporting documents shall be uploaded to the **Q38 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. Clinical Evaluation SOP(s) and PMCF Plan and report if available (or interim report). | | Company Response… | |
|  | Q38 Auditor Review: | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 39  S1 |  | **Chapter 6 Art 61.6 b**  Please provide a copy any relevant product-specific Common Specifications CS, where such is available in relation to devices listed in Chapter VI Article 61.6.  Supporting documents shall be uploaded to the **Q39 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. CS SOP(s). | | Company Response… | |
| Q39 Auditor Review: | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 40  S1 |  | **Chapter 6 Art 61.9**  **For ANNEX XVI devices only**  If relevant, please provide a copy of the relevant PMCF Plan, CER, PMS and any other Clinical documents or reports i.e. Clinical Investigation (CI) Plan (if equivalence is **not claimed**), contract, etc.  Supporting documents shall be uploaded to the **Q40 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.** | | Company Response… | |
| Q40 Auditor Review: | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| ***CLINICAL INVESTIGATIONS (CI) – ANNEX XV –*** | | | | | |
| 41  S2 |  | As per **MDR** **Preamble Whereas point (64);**  *The rules on clinical investigations should be in line with well-established international guidance in this field, such as the international standard ISO 14155:2011 on good clinical practice for clinical investigations of medical devices for human subjects…*  Please provide evidence that harmonised standard EN ISO 14155 has been incorporated into SOP(s) and other relevant documentation.  Supporting documents shall be uploaded to the **Q41 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. Clinical Investigation SOP(s). | | Yes  No | Confirm if no CI was carried out in support of MDR certification and no CI is currently planned in support of MDR certification. |
| Company Response… | |
| Q41 Auditor Review: | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 42  S2 |  | **Chapter 6 Article 61**  If a CI has been initiated or concluded within the last 24 months; please provide evidence of ethical approval and Competent Authority approval, etc.  Supporting documents shall be uploaded to the **Q42 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. Competent Authority Approval Evidence, etc. | | Company Response… | |
| Q42 Auditor Review: | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 43  **S2** |  | **Chapter 6 Article 62.2**  **Note: Only applicable to legal manufacturers outside of the EU.**  Please confirm who the legal person established in Union as legal representative, responsible for compliance and addressee of all communications (except where MS choose to demand only a contact person on their territory) is?  Supporting documents shall be uploaded to the **Q43 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. SOPs for control of legal person established in European Union as legal representative. | | Company Response… | |
| Q43 Auditor Review: | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 44  **S2** |  | **Chapter 6 Article 70.1**  Please provide a copy of the relevant Clinical Investigation SOP(s) with the relevant sections indicated/highlighted to demonstrate the following:  Prepare for use of new electronic system on clinical investigations for applications (submission to MS(s) where investigation is to be conducted, accompanied by documentation in Annex XIV; update of information within 1 week in case of changes) and for use of unique single identification number for all communication.  Supporting documents shall be uploaded to the **Q44 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. Electronic Submission SOP in relation to Clinical Investigation. | | Company Response… | |
| Q44 Auditor Review: | | | | Stage 1:  **Verified: Y/N** |
|  | Stage 2:  **Verified: Y/N** |
| 45  **S2** |  | **Chapter 6 Article 72**  Please provide a copy of the relevant Clinical Investigation SOP(s) (e.g. Recall SOP, Data handing SOP, Doc and data Retention SOP) with the relevant sections indicated/highlighted to demonstrate the following:  Put in place processes to monitor conduct of clinical investigation to verify protection of rights, safety and well-being of subjects, reliability/robustness of reported data, and compliance of conduct with MDR; determine extent of monitoring based on assessment of objective, methodology, and degree of deviation from normal clinical practice of investigation.  Establish procedure for emergency situations enabling immediate identification and (where necessary) immediate recall of devices used in investigation.  Supporting documents shall be uploaded to the **Q45 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. Clinical Investigation SOP(s) (e.g. Recall SOP, Data handing SOP, Documentation and data Retention SOP) | | Yes  No | Confirm if no CI was carried out in support of MDR certification and no CI is currently planned in support of MDR certification. |
| Company Response… | |
| Q45 Auditor Review: | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |

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| 46  S2 |  | **Chapter 6 Article 74**  Please provide a copy of the relevant PMCF / Clinical Investigation SOP(s) with the relevant sections indicated/highlighted to demonstrate the following:  Put in place process for notifying MS concerned via EUDAMED of clinical investigations to further assess CE marked devices within stated intended purpose (post-market clinical follow-up) at least 30 days prior to commencement if investigation would submit subjects to additional invasive or burdensome procedures.  Put in place process where if the scope of the CI is outside the intended purpose a CE marked device this CI shall be subject to all articles 62-81.  Supporting documents shall be uploaded to the **Q46 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. PMCF / Clinical Investigation SOP(s), EUDAMED SOP(s). | Company Response… | |
| Q46 Auditor Review: | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 47  **S2** |  | **Chapter 6 Article 75**  Please provide a copy of the relevant Clinical Investigation SOP(s) with the relevant sections indicated/highlighted to demonstrate the following:  Put in place process for notifying MS concerned via EUDAMED of intention to modify clinical investigations in ways that are likely to have substantial impact on safety, health or rights of subjects or reliability or robustness of clinical data generated, accompanied by updated documentation (Chapter II, Annex XV).  Supporting documents shall be uploaded to the **Q47 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.** | Company Response… | |
| Q47 Auditor Review: | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 48  **S2** |  | **Chapter 6 Article 77**  Please provide a copy of the relevant Clinical Investigation SOP(s) with the relevant sections indicated/highlighted to demonstrate the following:  **77. 1,2,3**  Put in place process for informing MSs concerned via EUDAMED of end / early termination / temporary halt of clinical investigation within 15 days [24 hours if halted/terminated on safety grounds].  **77. 4,5,7**  Put in place process for submission to MSs concerned via EUDAMED a clinical investigation report (Annex XV, Chapter I, Section 2.8) (within one year of end of clinical investigation/3 months from early termination) and summary of report (at latest within one year following provision of report, in style readily understood by intended user); reports shall become publicly available at latest when device is CE marked.  Supporting documents shall be uploaded to the **Q48 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.** | Company Response… | |
| Q48 Auditor Review: | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 49  **S2** |  | **Chapter 6 Article 80**  Please provide a copy of the relevant Clinical Investigation/ PMCF Investigation SOP(s) with the relevant sections indicated/highlighted to demonstrate the following:  Please provide evidence to show already in place process for recording **and** reporting of adverse events identified in clinical investigation / PMCF Investigation including serious adverse events; device deficiencies that might have led to serious adverse events in absence of suitable action/intervention/under less fortunate circumstances; or new findings concerning the above.  Supporting documents shall be uploaded to the **Q49 Folder.**  If more than one supporting document is being supplied, **please indicate the primary** **supporting document.**  Examples of supporting documents for this question may include e.g. Clinical Investigation/ PMCF Investigation SOP(s), etc. | Company Response… | |
| Q49 Auditor Review: | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |

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| **50** | **Q51 - Additional Documents for QMS Elements.** | | | |
| **EN ISO 13485: 2016** | **Confirm a copy of the following documents has been uploaded to the Q51 Additional Documents folder** | **QMS Documentation for MDR specific requirements** | |
| **A** | **4.2.4**  **4.2.5** | The Current Quality Manual  The Current Quality Policy  Document Control SOP(s)  Record Control SOP(s)  Document Retention SOP(s)  Current list of all SOP(s) and documents including revision number | Company Response… | |
| Auditor Review: | | Stage 1:  **Verified: Y/N** | |
| Stage 2:  **Verified: Y/N** | |
| **B** | **8.5.2**  **8.5.3**  **8.2.5** | Corrective and Preventive Action SOP(s)  A list of CAPA(s) opened or closed since the last audit of this site or within the last 12 months if this site has not previously been audited by the NSAI.  Control of nonconforming product/material procedure  Processes for monitoring and measurement of output, data analysis and product  improvement. | Company Response… | |
| Auditor Review: | | Stage 1:  **Verified: Y/N** | |
| Stage 2:  **Verified: Y/N** | |
| **C** | **7.4** | Purchasing procedures (Purchasing process, Supplier evaluation, selection, control and monitoring, Verification of purchased product/material, Current Approved vendors list or equivalent) | Company Response… | |
| Auditor Review: | | Stage 1:  **Verified: Y/N** | |
| Stage 2:  **Verified: Y/N** | |
| **D** | **5.6** | Management Review SOP  A copy of most recent complete MR records, including attendee list, agenda, minutes and quality objectives, presentation (if available) for example.  Evidence that Management Review incorporating the relevant MDR 2017/745 Requirements has taken place or…  is scheduled prior to the Stage 2 Audit (confirm date). | Company Response… | |
| Auditor Review: | | Stage 1:  **Verified: Y/N** | |
| Stage 2:  **Verified: Y/N** | |
| **E** | **8.2.5** | Internal Audit SOP  A copy of recent audit schedule  Evidence of completed Internal Audits incorporating the relevant MDR 2017/745 Requirements and…  if applicable evidence that the remaining IA’s are scheduled prior to the Stage 2 Audit. | Company Response… | |
| Auditor Review: | | Stage 1:  **Verified: Y/N** | |
| Stage 2:  **Verified: Y/N** | |
| **F** | **7.3** | Design and Development SOP(s) | Company Response… | |
| Auditor Review: | | Stage 1:  **Verified: Y/N** | |
| Stage 2:  **Verified: Y/N** | |
| **G** | **7.5** | Production, Process Control, and Servicing SOP(s) note if multiple SOPs exist, specific for Device subject to QMS assessment. | Company Response… | |
| Auditor Review: | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| **H** | **7.5** | Environmental Controls SOP(s) note if multiple SOPs exist, specific for Device subject to QMS assessment. | Company Response… | |
| Auditor Review: | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| **J** | **7.5** | Sterilisation Validation & Release SOP(s), Validation Report, Release record) note if multiple SOPs exist, specific for Device subject to QMS assessment. | Company Response… | |
| Auditor Review: | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |

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| **COMPLETED BY:** | | | | | | | |
| **Client Representative:** | | | | **Auditor:** | | | |
| **Name:** |  | **Date:** |  | **Name:** |  | **Date:** |  |

**For information use only: Summary of Key Clinical Activity Reports and Associated Timelines:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Clinical Activity** | **MDR Reference** | **Device Class** | **Frequency of Update** | **Reviewed by** |
| **CEP**  [Clinical Evaluation Plan] | Article 61 | All | As required; define in SOP | NB |
| **CER**  [Clinical Evaluation Report] | To be defined in SOP; may vary per Class |
| **CIP**  [Clinical Investigation Plan] | Articles 61 to 82 | All; if not claiming equivalence | | Approval by CA, Ethics Committee, etc., as appropriate |
| **CIR**  [Clinical Investigation Report] |
| **PMSP**  [Post-Market Surveillance Plan] | Article 84 | All | When necessary | N/A |
| **PMSR\***  [Post-Market Surveillance Report] | Article 85 | Class I | When necessary (frequency to justify) |
| **PSUR\***  [Periodic Safety Update Report] | Article 86 | Class Ilia | Every two years | NB |
| Class IIb | Every Year | NB (other than implants)  NB via EUDAMED (for implants) |
| Class III | Every Year | NB via EUDAMED |
| **PMCFP**  [Post-Market Clinical Follow-up Plan] | Annex XIV, Part B | Product-specific; so, a separate Plan for each product. |  |  |
| **PMCFER**  [Post-Market Clinical Follow-up Evaluation Report] |  |  |  |
| **SSCP**  [Summary of Safety and Clinical Performance] | Article 32 | Implantable and Class III | Every Year | Manufacturer to submit to NSAI |

**\*** PMSR and PSUR (or SOP/template) must be available during conformity assessment procedures, or via EUDAMED.

1. May be PRRC. [↑](#footnote-ref-1)