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| **INSTRUCTIONS** |
| **Important: Please read and follow these instructions carefully:**   * All documentation must be in English. * **Complete a full version of this form, for each secondary site included within the scope of the initial MDR 2017/745 application.** * **Before you begin, please ensure the accompanying ‘MDR Secondary Site 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: |  | | | | | | | | | | | |
| Headquarters Address: |  | | | | | | | | | | | |
| Management Representative: |  | | | | | | | | | | | |
| **Secondary Site (This form should only include information pertaining to this site)** | | | | | | | | | | | | |
| Company Name: |  | | | | | | | | | | | |
| Secondary Site Address: |  | | | | | | | | | | | |
| Contact Name: |  | | | | | | | | | | | |
| Telephone No.: |  | | | | | | | | | | | |
| E-mail Address: |  | | | | | | | | | | | |
| MDR Classification  (Of devices design/produced at this location) | Class Is | | Class Ir | Class Im | | | Class IIa | Class IIb  Non-Implant. | | Class IIb Implant. | | Class III |
|  | |  |  | | |  |  | |  | |  |
| Conformity Assessment Route (for this location) | ANNEX IX (Design + Production) | | | | ANNEX XI (Part A) (Production Only) | | | | ANNEX XVI (QMS for An XVI device) | | | |
| Activities performed at this Secondary Site |  | Management / Admin. | | |  | Regulatory Affairs | | |  | | Sterilisation Site | |
|  | Design / development | | |  | Production / Assembly | | |  | | Final QC / testing / Release | |
|  | Other Provide Details | | |  | | | | | | | |

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| **Secondary Site Information** |
| |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Products manufactured at this location**  **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*** |  |  |  |  |  |  |  |  |  |  | |

**B**

| **Before you begin:**   * **Please provide as much detail as possible in the Response/Evidence box for all questions.** * 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. * Please place supporting documents for the question in the corresponding folder. If placing more than one document in the folder – add “0PRIMARY” to the beginning of the file name of the primary document submitted. * Supporting documents include procedures, work instructions, and forms (specifications, protocols, test reports, etc.) * In each question select the appropriate option from the **“Choose and item”** listing (Applicable or Not applicable). Provide as much detail as possible for your answer. |
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**E**

| **Q** | **ANNEX I**  **GENERAL SAFETY AND PERFORMANCE REQUIREMENTS** | | |
| --- | --- | --- | --- |
| **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*** | | | |

| **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*** | | | |

| **Q** | **ANNEX I**  **GENERAL SAFETY AND PERFORMANCE REQUIREMENTS** | | | | |
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| **EN ISO:**  **13485**  **:2016** | **MDD 93/42/ EEC,**  **AIMD**  **90/385/EEC,**  **MEDDEV’s** | **MDR Requirement** | **Response/Evidence** | **Auditor verification**  ***For office use only*** |
| ***CHAPTER I, GENERAL REQUIREMENTS*** | | | | | |

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| **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**  Is the site involved in establishing MDR Product/Safety Requirements or Risk Management?  Typical examples include: Prepares GSPR list (Contract Design & Development) Prepares Risk/Hazard Analysis (Contract Design & Development) Post Production Risk Analysis (Contract Manufacturer)  Supporting documents shall be uploaded to the **Q1 Folder.**  Examples of supporting documents include MDR GSPR Checklist and MDR Technical File SOP, Risk Management SOPs, Risk/Hazard Analysis form, etc. | Choose an item. | |
| 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.**  Is the site involved in establishing and or verifying performance characteristics of the finished device over its lifetime?  Typical examples include: Responsible for Real Time or Accelerated Aging (Contract Design & Development/Production) Responsible for Functional/Life Testing (Contract Design & Development/Production) Responsible for Packaging/Transit Testing (Contract Design & Development/Production)  Supporting documents shall be uploaded to the **Q2 Folder.** | Choose an item. | |
| 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**  Is the site involved in introducing or reducing the levels of 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>  Typical examples include: CMR Residuals Testing Validation (Contract Design & Development/Production) Leechables Testing Validation (Contract Design & Development/Production) CMR Residual / Leechables Risk Management Report (Contract Design & Development/Production) Supporting documents shall be uploaded to the **Q3 Folder.** | Choose an item. | |
| 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**  Is the site involved in establishing/testing for ‘suitability of use’ requirements including: 14.1 Connections/Misconnection/Gas Transfer, etc. 14.2 Electromagnetic / Radiation Effects 14.7 Safe disposal after use  Supporting documents shall be uploaded to the **Q4 Folder.** | Choose an item. | |
| 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**  Is the site responsible for establishing/testing for *'precision accuracy and stability*’ for *'diagnostic devices*' are addressed.  Typical examples include:   * Precision vital signs monitoring final test (Contract Design & Production) Calibration of vital signs monitor (Contract Design & Production)   Supporting documents shall be uploaded to the **Q5 Folder.** | Choose an item. | |
| 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**  Is the site responsible for design and development, deployment, and or support of software/web or mobile apps which by themselves are a medical device, or are used with a medical device? If so, please demonstrate how the new MDR requirements for Section 17 have been addressed?  Typical (Contract Design/Deployment) Examples include:   * Software Development Life Cycle Files * Pre and Post Production Cybersecurity Risk; * Scalability/Stress Testing   Supporting documents shall be uploaded to the **Q6 Folder**. | Choose an item. | |
| 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 to this site** 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 Folde**r.  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. | Choose an item. | |
| 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**  Is the site responsible for MDR requirements for Labels and IFU (Section 23)?  Is the site responsible for translation of labels and IFU in other languages?  Is the site responsible for SOPs for Label control, IFU control / website/electronic IFU if appropriate, IFU and label translation SOP, draft set of labels in English etc.  Supporting documents shall be uploaded to the **Q8 Folder.** | Choose an item. | |
| 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*** |
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| **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**  Does the site have a separate Quality Manual or Quality Manual Supplement?  Are there MDR requirements, policies, responsibilities in the separate QM or Supplement?  Supporting documents shall be uploaded to the **Q9 Folder.** | Choose an item. | | |
| 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 site act as the Authorised Representative (AR)?  If so, provide details.  Supporting documents shall be uploaded to the **Q10 Folder.** | Choose an item. | | |
| 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]**  Confirm if the site is responsible or involved in **design** **and or manufacturing activities**, manufacturing process validations, management of design etc.  Please provide specific references to complete information and specifications, including 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.**  Examples of supporting documents for this question may include e.g. Manufacturing process validations, Design Change Procedure, other relevant change procedures, etc. | Design Activities present on Site Choose an item. | | |
| Manufacturing Activities present on Site Choose an item. | | |
|  | **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. | Batch Verification on Site Choose an item. | | |
| 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. | Choose an item. | | |
| 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**  Is the site responsible for retaining relevant documents 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?  Supporting documents shall be uploaded to the **Q13 Folder.** | Choose an item. | | |
| 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*** |
| --- | --- | --- | --- | --- | --- |
| **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**  Does the site have a separate Quality Manual or Quality Manual Supplement?  Are there MDR requirements, policies, responsibilities in the separate QM or Supplement?  Supporting documents shall be uploaded to the **Q14 Folder**. | Choose an item. | | |
| Q14 Auditor Review: | | | Stage 1:  **Verified: Y/N** | |
| Stage 2:  **Verified: Y/N** | |
| 15  S1 | NA | **ANNEX XI Part A 6.4**  Is the site responsible for informing 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~~.~~** | Choose an item. | | |
| Q15 Auditor Review: | | | Stage 1:  **Verified: Y/N** | |
| Stage 2:  **Verified: Y/N** | |
| 16  S2 | 4.2.3 | **ANNEX XI Chapter Part A 8 Batch Verification**  Is the site responsible for, 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; evidence of Batch History/Record control.    Supporting documents shall be uploaded to the **Q16 Folder.** | Choose an item. | | |
| 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 site act as the Authorised Representative (AR)?  If so, provide details.  Supporting documents shall be uploaded to the **Q17 Folder.** | Choose an item. | | |
| 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**  Is the site responsible for device specifications, maintenance of design dossier and or technical documentation?  Supporting documents shall be uploaded to the **Q18 Folder.** | Choose an item. | |
| Q18 Auditor Review: | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |

|  | **ANNEX IV**  **EU DECLARATION OF CONFORMITY (Including Article 19)** | | | |
| --- | --- | --- | --- | --- |
| **EN ISO:**  **13485**  **:2016 / Directive** | **MDR Requirement** | **Client Response and supporting evidence** | |
| 19  S2 |  | **ANNEX IV - EU Declaration of Conformity**  Is the site responsible for drafting/issuing/controlling/maintaining EU Declaration(s) of Conformity (DoC) 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.** | Choose an item. | |
| Q19 Auditor Review: | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 20  S2 |  | **Chapter 2 Article 19 Declaration of Conformity**  Is the site responsible for conformance with other European Union legislations (e.g. REACH, RoHS, WEEE, etc.) e.g. incorporating info into DoC’s as per Article, 19.2?  Supporting documents shall be uploaded to the **Q20 Folder.** | Choose an item. | |
| 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 | | **ANNEX VI PART A – 1.1-1.4**  Is the site responsible for the registration in EUDAMED of Economic Operators (EO) i.e., Authorised Representative, Importer, Distributor and PRRC.  Supporting documents shall be uploaded to the S1Q21 Folder.  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.  Supporting documents shall be uploaded to the **Q21 Folder.**  https://ec.europa.eu/health/sites/health/files/md\_sector/docs/2020-15-position-paper-actor-registration-module\_en.pdf | Choose an item. | |
| 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**  Is the site responsible for UDI-DI requirements, including but not limited to UDI-DI creation and application, UDI-DI maintenance and overall controls for the UDI and or UDI labelling process.  Supporting documents shall be uploaded to the **Q22 Folder.** | Choose an item. | |
| 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** | | | |
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| **EN ISO:**  **13485**  **:2016 / Directive** | **MDR Requirement** | **Client Response and supporting evidence** | |
| 23  S2 | NA | **Chapter 2 Article 7: Claims**  Is the site responsible for advertising in the EU (including website) to show evidence of compliance to the requirements of Chapter 2 Article 7.  Supporting documents shall be uploaded to the **Q23 Folder.** | Choose an item. | |
| Q23 Auditor Review: | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 24  S1 | NA | **Chapter 2 Article 9: Common Specifications (CS).**  If applicable, is the site responsible for incorporation of Common Specifications 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.** | Choose an item. | |
| Q24 Auditor Review: | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 25  S1 | NA | **Chapter 2 Article 10, General obligations of manufacturers**  Section 15  Is the site responsible for 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.** | Choose an item. | |
| Q25 Auditor Review: | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 26  S2 | NA | **Chapter II Article 10, Section 16**  Is the site responsible for insurance policy which includes cover for product liability claims?  Supporting documents shall be uploaded to the **Q26 Folder.** | Choose an item. | |
| Q26 Auditor Review: | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 27  S2 | NA | **Chapter 2 Article 13 General Obligations of importers.**  Does the site act as the importer, or is responsible for the importer?.  Supporting documents shall be uploaded to the **Q27 Folder.** | Choose an item. | |
| Q27 Auditor Review: | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 28  S2 | NA | **Chapter 2 Article 14 General Obligations of Distributors.**  Does the site act as the distributor or is responsible for the distributor?.  Supporting documents shall be uploaded to the **Q28 Folder.** | Choose an item. | |
| Q28 Auditor Review: | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 29  S1 | NA | **Chapter 2 Article 15. Person responsible for regulatory compliance**  Does an individual at the site act as the PRRC and if so, provide evidence of how they meet compliance to Article 15.1 a and/or b.  If instead, the site is 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.** | Choose an item. | |
| Q29 Auditor Review: | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 30  S2 | NA | **Chapter 2 Article 17 Single-use devices and their reprocessing**  Does the site reprocess single use devices, or is responsible for reprocessing?  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.**  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. | Choose an item. | |
| Q30 Auditor Review: | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 31  S2 | NA | **Implantable Devices only**  **Chapter 2 Article 18 Implant Card and information to be supplied to the patient with an implanted device**.  Is the site responsible for compliance to the requirements for Implant cards and patient information as per Article 18.  Supporting documents shall be uploaded to the **Q31 Folder.**  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. | Choose an item. | |
| Q31 Auditor Review: | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 32  S2 | NA | **Chapter 2 Article 23 Parts and components**  Is the site responsible for the servicing and or 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.**  Examples of supporting documents for this question may include e.g. Repair SOP(s), Servicing SOP(s), etc. | Choose an item. | |
| 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  S1 | **MDD** Annex X 1.1(c) | Is the site responsible for the 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… | | Choose an item. | | |
| Q33 Auditor Review: | | | | Stage 1:  **Verified: Y/N** | |
| Stage 2:  **Verified: Y/N** | |
| 34  S1 | NA | Is the site responsible for 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.** | | Choose an item. | | |
| Q34 Auditor Review: | | | | Stage 1:  **Verified: Y/N** | |
| Stage 2:  **Verified: Y/N** | |
| 35  S1 | NA | **Chapter VII Articles 87-89**  Is the site responsible for the Vigilance reporting system in place to show compliance with Articles 87-89 and already in place current MED DEV 2.12 requirements.  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. | | Choose an item. | | |
| 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)**  Is the site responsible for Clinical Evaluation, Risk Management (RM), PMS and Post Market Clinical Follow-up (PMCF)   * 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.**  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. | | Choose an item. | |
|  | 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)**  Is the site responsible for 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.**  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. | | Choose an item. | |
|  | 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)**  Is the site responsible for 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.**  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). | | Choose an item. | |
|  | Q38 Auditor Review: | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 39  S1 |  | **Chapter 6 Art 61.6 b**  Is the site responsible for 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.**  Examples of supporting documents for this question may include e.g. CS SOP(s). | | Choose an item. | |
| 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**  Is the site responsible for 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.** | | Choose an item. | |
| 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…  Is the site responsible for clinical investigations in the EU? 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.**  Examples of supporting documents for this question may include e.g. Clinical Investigation SOP(s). | | Choose an item. | |
| Q41 Auditor Review: | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 42  S2 |  | **Chapter 6 Article 61**  Is the site responsible for clinical investigations in the EU? 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.**  Examples of supporting documents for this question may include e.g. Competent Authority Approval Evidence, etc. | | Choose an item. | |
| 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.**  Does the site act 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.**  Examples of supporting documents for this question may include e.g. SOPs for control of legal person established in European Union as legal representative. | | Choose an item. | |
| Q43 Auditor Review: | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 44  **S2** |  | **Chapter 6 Article 70.1**  Is the site responsible for Clinical Investigations in the EU 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.** | | Choose an item. | |
| Q44 Auditor Review: | | | | Stage 1:  **Verified: Y/N** |
|  | Stage 2:  **Verified: Y/N** |
| 45  **S2** |  | **Chapter 6 Article 72**  Is the site responsible for 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.**  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). | | Choose an item. | |
| Q45 Auditor Review: | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 46  S2 |  | **Chapter 6 Article 74**  Is the site responsible for 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.**  Examples of supporting documents for this question may include e.g. PMCF / Clinical Investigation SOP(s), EUDAMED SOP(s). | | Choose an item. | |
| Q46 Auditor Review: | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 47  **S2** |  | **Chapter 6 Article 75**  Is the site responsible for Clinical Investigation or notifying EUDAMED 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.** | | Choose an item. | |
| Q47 Auditor Review: | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 48  **S2** |  | **Chapter 6 Article 77**  Is the site responsible for Clinical Investigation or notifying EUDAMED 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 lap when device is CE marked.  Supporting documents shall be uploaded to the **Q48 Folder.** | | Choose an item. | |
| Q48 Auditor Review: | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| 49  **S2** |  | **Chapter 6 Article 80**  Is the site responsible for 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.**  Examples of supporting documents for this question may include e.g. Clinical Investigation/ PMCF Investigation SOP(s), etc. | | Choose an item. | |
| Q49 Auditor Review: | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |

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| **50** | **Q50 - Additional Documents for QMS Elements.** | | | | |
| **EN ISO 13485: 2016** | **Confirm a copy of the following documents has been uploaded to the Q50 Additional Documents folder for the SITE if different from the Primary Site** | **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 | Choose an item. | | |
| 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. | Choose an item. | | |
| 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) | Choose an item. | | |
| 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). | Choose an item. | | |
| 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. | Choose an item. | | |
| Auditor Review: | | | | Stage 1:  **Verified: Y/N** |
| Stage 2:  **Verified: Y/N** |
| **F** | **7.3** | Design and Development SOP(s) | Choose an item. | | |
| 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. | Choose an item. | | |
| 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. | Choose an item. | | |
| 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. | Choose an item. | | |
| 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 IIa | 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 | Implantables 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.