

**Medical Devices**

**Application Form**

* **Class 2A**
* **Class 2B Non-Implantable**

**NEW**

**Please tick all that apply:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Class 2A | | |  |  |
|  | Class 2B Non-Implantable | | |  |  |
|  |  | | |  |  |
|  | Transfer (from another NB) | | |  |  |
|  | Modular (partial application) | | |  |  |
|  |  | | |  |  |
|  | Fast Track (expedited) | | |  |  |
|  | | | | | |
| PO Number | |  | | | |
|  | | | | | |
| **Directive(s) that apply:** | | | **NSAI File Number** | | |
|  | MDD (93/42/EEC) | | 252.     / | | |

|  |  |
| --- | --- |
| Legal Manufacturer’s Name |  |
| Legal Manufacturer’s Address |  |

|  |
| --- |
| INSTRUCTIONS |
| 1. Please complete all relevant sections of the form (excluding the NSAI Review sections). 2. Please enter as much information onto the form as possible - avoid entering “see Technical File/Design Dossier”. If the data is in the supporting documentation, please ensure that there is a clear reference to the exact location of this information. 3. Please submit an unsigned version of this Application in Word as well as a signed copy - either scanned/secured (pdf) copy. 4. All application forms and supporting data to be forwarded in soft copy via one of the following (Hard copies not required)   NSAI upload facility : see <http://www.nsaiinc.com/>   1. Supporting documents should be provided in a SEARCHABLE format 2. Applications and supporting documentation must be in English 3. Please send a representative sample of the device(s). This is particularly important for new/novel devices. Any video or animations of procedures/simulated use would also be helpful, if available. |

Table of Contents

[INSTRUCTIONS 2](#_Toc497733481)

[APPLICANTS’ SUBMISSION CHECKLIST 4](#_Toc497733482)

[DECLARATION(S) BY APPLICANT 5](#_Toc497733483)

[SECTION 1: MANUFACTURER AND PRODUCT DETAILS 6](#_Toc497733484)

[SECTION 2: DESCRIPTION OF DEVICE 8](#_Toc497733485)

[SECTION 3: INTENDED USE OF THE DEVICE 8](#_Toc497733486)

[SECTION 4: PREVIOUS EXISTING LEGISLATION 9](#_Toc497733487)

[SECTION 5: DESIGN AND MANUFACTURING OVERVIEW 9](#_Toc497733488)

[SECTION 6: LABELLING AND IFU 10](#_Toc497733489)

[SECTION 7: SOLUTIONS TO ESSENTIAL REQUIREMENTS AND HARMONISED STANDARDS 11](#_Toc497733490)

[SECTION 8: PERFORMANCE/COMPLAINT ANALYSIS 12](#_Toc497733491)

[SECTION 9: RISK MANAGEMENT 13](#_Toc497733492)

[SECTION 10: STERILISATION & STABILITY 14](#_Toc497733493)

[10.1 STERILISATION VALIDATION 14](#_Toc497733494)

[10.2 MAINTENANCE OF STERILITY & STABILITY (PACKAGING & DEVICE) OVER SHELF LIFE 16](#_Toc497733495)

[SECTION 11: BIOCOMPATIBILITY 17](#_Toc497733496)

[SECTION 12: MEDICAL ELECTRICAL EQUIPMENT, SYSTEMS & SOFTWARE 19](#_Toc497733497)

[SECTION 13: CLINICAL PERFORMANCE 23](#_Toc497733498)

[13.1 CLINICAL EVALUATION 23](#_Toc497733499)

|  |  |
| --- | --- |
| APPLICANTS’ SUBMISSION CHECKLIST | |
|  | Completed application form (Word format, .doc or .docx) |
|  | Application (min. Signed Declaration page(s)) scanned |
|  | QMS certificates for all sites in Table 1 |
|  | Draft Declaration of Conformity |
|  | Labelling & IFU – May be Drafts |
|  | Essential Requirements Checklist |
|  | Performance/Complaint Analysis |
|  | Risk Management documentation |
|  | Sterilisation Validation(s) – if sterile/intended to be sterilised |
|  | packaging and device stability data – if necessary |
|  | Biocompatibility data – if necessary |
|  | Electrical Safety Testing data – if necessary |
|  | Software/firmware lifecycle documents – if necessary |
|  | Bench Testing data – if necessary |
|  | Clinical Evaluation Report(s) per MEDDEV 2.7.1 |
|  | Clinical Evaluation procedure |
|  | Clinical investigation(s) report(s) and supporting documents per MEDDEV |
|  | Literature search protocol |
|  | Literature Search Report |
|  | Please include PMCF plan in the CER |
| **2.7.1.** | |
|  | Clinical evaluation report as per MEDDEV 2.7.1 |
|  | if following literature review/ equivalent device route. please complete and attach NSAI Equivalence form GRF-25-28 . |
| **For Transfers** | |
|  | Copy of existing Notified Body Certificate(s) |
|  | Transition Plan |
|  | Contact details for existing Notified Body |
| ***(NSAI will not contact the existing Notified Body***  ***prior to agreement with the Manufacturer)*** | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| DECLARATION(S) BY APPLICANT | | | | | | |
| In making this application we declare:   * The information in this form is correct * We have not lodged an application with any other notified body to undertake conformance assessment procedures for the same product(s) / device-related quality system mentioned. * We undertake to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective actions and notifications, taking account of the nature and risks in relation to this product. * We agree to provide all vigilance reports to the Competent Authorities and NSAI * We agree to pay all applicable fees and understand that non-payment of fees will result in withdrawal of approval. * We undertake to fulfil the obligations imposed by the quality system approved * We undertake to keep the approved quality system adequate and efficacious. * We agree to inform NSAI that approved the quality system of any plan for substantial changes to the quality system or the product-range covered. * We shall submit to NSAI any changes to the approved design, wherever the changes impact conformity with the essential requirements of the Directive or with the conditions prescribed for the use of the device. * We authorise NSAI to carry out all the necessary inspections at the legal manufacturer, critical sub contractors and / or crucial supplier facilities and will supply NSAI with all relevant information to accomplish the above and in particular the following: * The documentation on the quality system * The data stipulated in the part of the quality system relating to design, such as the results of analyses, calculations, tests etc., (where relevant) * The data stipulated in the part of the quality system relating to manufacture such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc. * We authorize and agree to allow NSAI access to all critical subcontractors and crucial suppliers, and all sites where the device or it’s crucial components are produced. * We agree to allow NSAI access to the Legal Manufacturer’s premises, and /or any of the above listed sites at any time for the purposes of performing unannounced audits. * As necessary we agree to provide all necessary support in acquiring the necessary travel papers, including VISA, to facilitate NSAI access to the above listed locations. * We agree to inform NSAI of the periods when the devices identified in this application will not be manufactured. * We understand that NSAI may end this contract with the Legal Manufacturer if permanent unannounced access to the above listed sites is no longer assured. * We understand that NSAI may cancel any unannounced audit at any time if the safety and security of NSAI personnel cannot be assured. | | | | | | |
| **By signing below, I accept the above declarations** | | | | | | |
| Signed  on behalf of the Manufacturer: | |  | | Date: | |  |
| Name (please print): | |  | | | | |
| Position / Title: | |  | | | | |
| Contact person  (if different to Manufacturer): | |  | | | | |
| e-mail: |  | | Phone: | |  | |

|  |
| --- |
| Section 1: Manufacturer and Product Details |
| Note the “Manufacturer” as defined by the Directive(s) is “the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party. |

| **Table 1 – Manufacturers Information & Summary Product Data** | | | | | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Legal Manufacturer’s Name | | | | | | | | |  | | | | | |
| Legal Manufacturer’s Address | | | | | | | | |  | | | | | |
| Design Site(s): | | | | | | | | |  | | | | | |
| Manufacturing Site(s):  (i.e. sites of actual manufacture) | | | | | | | | |  | | | | | |
| Assembly Site(s) if applic.: | | | | | | | | |  | | | | | |
| Sterilisation Site(s) if applic.: | | | | | | | | |  | | | | | |
| Scope of Site(s):  (i.e. as shown on the QMS cert) | | | | | | | | |  | | | | | |
| Name and address of EU Authorised Representative  (if applicable) | | | | | | | | |  | | | | | |
|  | | | | | | | | |  | | | | | |
| Product/Product Family Name:  (In compliance with NB/MED/2.5.1/REC4 & NBOG’S Best Practice Guide 2006-2) | | | | | | | | |  | | | | | |
| GMDN Reference Number: | | | | | | | | |  | | | See [www.gmdnagency.com](http://www.gmdnagency.com) | | |
|  | Declaration of Conformity included - Location within submission : | | | | | | | | | | |  | | |
| Class | |  | IIa | | |  | IIb | | | | Rule(s) | | |  |
| Rationale | |  | | | | | | | | | | | | |
| Conformity Assessment | | Annex | |  | II | | | Annex | |  | V | | | |
| Full QA | | | | | | Prodn QA | | | | |  | |
| Date of this application  (i.e. date of Declaration of Applicant): | | | | | | | |  | | | | | | |

| Please complete the Table below, providing a full and up-to-date list of the current model numbers and descriptions related to this Application.  If the Declaration of Conformity is being used (instead of completing Table 2), please make sure that the WORD version is supplied. | | | |
| --- | --- | --- | --- |
| Table 2 – Product Family Information | | | |
| **Sub-Family** | **Model/Catalogue Number** | **Description** | **Class** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

| SECTION 2: DESCRIPTION OF DEVICE |
| --- |
| Please provide a full description of the device which demonstrates that the product is covered under the relevant Directive: |
| Device Description: |

| SECTION 3: INTENDED USE OF THE DEVICE | |
| --- | --- |
| 1. | Please enter a full description of the intended use of the device, which supports the product classification: |
|  |
| 2. | List of any contra-indications : |
|  |
| 3. | List of any precautions / warnings : |
|  |

| Section 4: Previous Existing Legislation | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| 1. | Does the device have any existing approvals (e.g. FDA 510(k)) | |  | Yes |  | No |
| 2. | If “Yes” – please advise |  | | | | |
| 3. | Does this product, labelled with your Name & Address carry CE Marking with another Notified Body | |  | Yes |  | No |
| If “Yes” – this is considered a TRANSFER  Please refer to applications checklist on page #5 | | | | | |

| **SECTION 5: DESIGN AND MANUFACTURING OvERViEW** | |
| --- | --- |
| 5.1 | Please provide evidence of design development documentation – including design and development plan (if available), design input to output matrix (or similar), product specification: |
| ***Click here to enter text.*** |
| 5.2 | Please provide evidence of the following in relation to the manufacturing process:   * List of manufacturing processes and validation status * Product specification or product release criteria |
| ***Click here to enter text.*** |

| Section 6: Labelling and IFU | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. | 1. Location of the sample Label(s) & IFU 2. in the supporting documentation | |  | | | | | |
| **Please include all levels of labelling – device, packaging, carton, etc.**  Note - Draft labelling is acceptable for New Applications | | | | | | | |
| 2. | Are copies of all labelling provided? | | | |  | Yes |  | No |
| If No please rationalize that the sample provided is representative of the family | | | | | | | |
| 3. | Is the IFU being provided electronically? | | | |  | Yes |  | No |
| If “Yes”, please submit evidence of compliance with Council Regulation 207-2012 for electronic IFU. | | | | | | | |
| 4. | Are symbols being utilized in product labeling or IFU’s . | | | |  | Yes |  | No |
| If yes are symbols in compliance with– | | | | | | | |
| EN 1041: |  | | EN ISO 980: |  | | | |
|  | If compliance with these vertical labelling standards is not claimed, please justify - | | | | | | | |
|  | | | | | | | |
| 5. | If an IFU is not provided(Class 2A only) please rationalize how the device can be used safely in the absence of such instructions | | | | | | | |
|  | | | | | | | |

| Section 7: Solutions to Essential Requirements and Harmonised Standards | | | | | |
| --- | --- | --- | --- | --- | --- |
| 1. | State Location of the solutions to Essential Requirements in the supporting documentation: | | | | |
|  | | | | |
| The recommended format for the Essential Requirements Checklist is shown in the GHTF Document GHTF/SG1/N011:2008 (STED).  Manufacturers should include **Reference to supporting controlled documents -** this column should contain the reference to the actual technical documentation that demonstrates conformity to the essential requirement(s), i.e. the certificates, test reports, validation reports, study reports or other documents that resulted from the method used to demonstrate conformity and its location within the Technical File/Design Dossier. | | | | |
| 2. | Are Harmonised Standards being used |  | Yes |  | No |
| If “No” please justify - | | | | |
|  | | | | |
| 3. | Please list the relevant Harmonised Standards in Table 3 below | | | | |
| | **TABLE 3 – Applicable Harmonised Standards List** | | | | --- | --- | --- | | **Standard** | **Year** | **Has the Standard been applied in full**  **Yes / No** | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | | | | | |

| Section 8: PERFORMANCE/COMPLAINT ANALYSIS | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 1. | Is there a product history for this device | | |  | Yes |  | No |
| If “No” please identify equivalent device(s) and relevant performance data | | | | | | |
|  | | | | | | |
| a. | What is the time period of the data being provided – |  | | | | |
| b. | **What are the:** | | | | | |
| Total no. units placed on the market worldwide) |  | | | | |
| Total no. of complaints worldwide |  | | | | |
| Total Number of EU Vigilance Reports |  | | | | |
| 2. | Please provide: | | | | | | |
|  | Trended analysis (graphical form) of the data over the stated period of time. | | | | | |
|  | Summary table of the individual complaints, with quantity and % total sales | | | | | |
| 3. | Please summarize all global Vigilance issues that fulfill the European Reporting requirements in the following/similar format: | | | | | | |
| | **TABLE 4:** | | | | | | | --- | --- | --- | --- | --- | --- | | **Report No.** | **Competent Authority** | **Details of investigation** | **Root Cause** | **CAPA Raised**  **Y/N**  **Details** | **Status** | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  |   **Note: Please supply this table as an attachment to the submission** | | | | | | |

| Section 9: Risk Management | | | | | |
| --- | --- | --- | --- | --- | --- |
| **1.** | Is Compliance being claimed to EN ISO 14971 2012 |  | Yes |  | No |
| **2.** | Please provide the document number of the Risk Analysis Matrix / Risk assessment summary matrix/documents and location within the technical file supplied - | | | | |
|  | | | | |
| **3.** | Please provide a traceability matrix linking the contraindications, warnings and precautions from Risk Management File to the Instructions For Use and CER | | | | |
|  |  | | | | |

| Section 10: Sterilisation & Stability | | | | | | | | | | | | | | | | | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 10.1 Sterilisation Validation | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **For devices provided sterile** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **1.** | Please provide the necessary sterilisation validation protocol(s) & report(s) and populate Table 5 below | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | Initial validation information: Year | | | | | | | | | | | | | | | | | | | | | | | |
|  | | Latest revalidation (if initial validation >1yr) | | | | | | | | | | | | | | | | | | | | | | | |
| | **Table 5 – Sterilisation Information Summary** | | | | | | | --- | --- | --- | --- | --- | --- | | **Device**  **sub-family** | **Cat.**  **Number** | **Sterilisation Method** | **Sterilisation Location** | **Protocol / Report No.** | **Site Resp for Release** | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | 1. | Is EtO used for Sterilisation of the device(s)  If “No” please go to Question #2 below. | | | | | | | | | | | | | | | | |  | | Yes | | |  | | No |
| Is compliance with EN ISO 10993-7 latest version claimed | | | | | | | | | | | | | | | | |  | | Yes | | |  | | No |
| If “No” please explain | | | | |  | | | | | | | | | | | | | | | | | | | |
| Is compliance with EN ISO 11135 latest version claimed | | | | | | | | | | | | | | | | |  | | Yes | | |  | | No |
| If “No” please explain | | | | |  | | | | | | | | | | | | | | | | | | | |
| Please categorise the device according to the duration of contact | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | A – Limited Exposure | | | | | | | | | | | | | | | | | | | | | | |
|  | | B – Prolonged Exposure | | | | | | | | | | | | | | | | | | | | | | |
|  | | C – Permanent Contact | | | | | | | | | | | | | | | | | | | | | | |
|  | 2. | Is irradiation used for Sterilisation of the device(s)  If “No” please go to Question #3 below. | | | | | | | | | | | | | | | | |  | | Yes | | |  | | No |
| a. | Is compliance with EN ISO 11137 latest version claimed | | | | | | | | | | | | | | | |  | | Yes | | |  | | No |
| If “No” please explain: | | | | | | |  | | | | | | | | | | | | | | | | |
|  | | | Gamma | | | | | | |  | | | E-Beam | | | | | | | | | | |
| b. | What Dose setting method(s) are used | | | | | | | | | | | | | | | | | | | | | | | |
|  | | VDMAX25 | | | |  | | Method 1 | | | | | | |  | | Method 2 | | | | | | |
| 3 | Is moist heat used for Sterilisation of the device(s)  If “No” please go to Question #4 below. | | | | | | | | | | | | | | | |  | | Yes | |  | | | No | |
| Is compliance with EN ISO 11138 latest version claimed | | | | | | | | | | | | | | | |  | | Yes | |  | | | No | |
| If “No” please explain | | | | | |  | | | | | | | | | | | | | | | | | | |
| What cycle type used | | | | | | | | | |  | | Pre-vac | | |  | | Gravity | | | |  | | Other | |
| Details if “Other” – | | | | | |  | | | | | | | | | | | | | | | | | | |
|  | 4. | If one of the above methods is not used, please describe the method –  (e.g. Dry heat, Aseptic Fill, Liquid Chemical, etc.) and list the standard(s) applied | | | | | | | | | | | | |  | | | | | | | | | | | |

| **Section 10: Sterilisation & sTABILity** | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 10.2 Maintenance of Sterility & Stability (Packaging & Device) over shelf life | | | | | | | | |
| 1. | Please define the shelf life/expiry date | | | | Years | | | |
| 2. | Please confirm the number of sterilisation cycles that the device and packaging were subjected to prior to stability testing - | | | |  | | | |
| 3. | Please describe the preconditioning applied (eg. Ageing, transport etc): | | | |  | | | |
| 4. | Is compliance with EN ISO 11607 latest version claimed | | |  | | Yes |  | No |
| If “no” please justify: |  | | | | | | |
| 5. | If submitting Accelerated Aging data to support Shelf life, please confirm start date and expected completion date for real time Packaging & Device studies | | | | | | | |
|  | |  | | | | | |
| 6. | Please list and supply all relevant reports which substantiate Packaging & Device shelf life – | | | | | | | |
|  | | | | | | | |

| Section 11: BIOCOMPATIBILITY | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Please confirm the categorisation of the devices with respect to Body Contact and Duration of Contact in Table 6 below & the testing conducted in Table 7 | | | | | | |
| 1. | Is compliance with EN ISO 10993-1 latest version claimed | |  | Yes |  | No |
| If “no” please justify: |  | | | | |
| 2. | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Table 6a – Biocompatibility Categorisation : Body Contact** | | | | | | | **Surface-contacting devices** | | **External communicating devices** | | **Implant devices** | | |  | Skin |  | Blood path, indirect |  | Tissue/bone | |  | Mucosal membranes |  | Tissue/bone/dentin |  | Blood | |  | Breached/compromised surfaces |  | Circulating blood |  | | | | | | | |
| 3. | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Table 6b – Duration of Contact** | | | | | | |  | Limited exposure  (< 24hrs) |  | Prolonged exposure  (>24hrs <30 days) |  | Permanent contact (>30 days) | | | | | | |

| **Section 11: BIOCOMPATIBILITY** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Please confirm the categorisation of the devices with respect to Body Contact and Duration of Contact in Table 6 below & the testing conducted in Table 7 | | | | | | |
| 4. | | Table 7 – Tests considered/done | | | | | | | --- | --- | --- | --- | --- | --- | | Tests to be considered | ISO 10993 series  Year | Test completed by | Report number | Date | Conclusion | | Cytotoxicity | -5 : |  |  |  |  | | Sensitisation  (Delayed type hypersensitivity) | -10 : |  |  |  |  | | Irritation or intra-cutaneous reactivity | -10 : |  |  |  |  | | Systemic toxicity (Acute)  pyrogenicity | -11 : |  |  |  |  | | Sub-chronic toxicity (sub acute toxicity) | -11 : |  |  |  |  | | Genotoxicity  mutagenicity | -3 : |  |  |  |  | | Implantation | -6 : |  |  |  |  | | Haemo-compatibility | -4 : |  |  |  |  | | Chronic toxicity | -11 : |  |  |  |  | | Carcinogenicity | -3 : |  |  |  |  | | Reproductive and developmental toxicity | -3 : |  |  |  |  | | Biodegradation | -9 : |  |  |  |  | | Toxicokinetic studies | -16 : |  |  |  |  | | Immunotoxicology | -20 : |  |  |  |  | | Other Tests |  |  |  |  |  | | | | | | |
| 5. | Has testing been done on finished/sterilized device(s), or on materials that have been processed in the same manner, including sterilization | |  | Yes |  | No |
| If “no” please justify: |  | | | | |
| 6. | Have biocompatibility test results been assessed and deemed acceptable by a competent individual? | | | | | |
|  | | | | | |

| Section 12: Medical Electrical Equipment, Systems & SOFTWARE | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| 1. | Is the product ME Equipment or System | |  | Yes |  | No |
| **Please answer all questions below and complete Tables 8, 9 & 10**  **Please provide all relevant Test Reports, and EN 62304 Software Development Process & Validation Report, as well as Software Risk Assessment.** | | | | | | |
| 2. | Have the applicable requirements of EN 60601-1 latest version, including the mandatory risk assessment to EN 14971 been applied | |  | Yes |  | No |
| If “No”, is a particular standard (60601-2-xx) applicable that refers to a prior 60601-1 (ex. 2nd edition)? | |  | Yes |  | No |
| If “Yes” – please list all applicable “Part 2’s” in Table 9 below | | | | | |
| If “No” – please provide rationale for not applying the latest version of EN 60601-1 – | | | | | |
|  | | | | | |
| 3. | Please list the document(s) submitted substantiating conformance to the edition of EN 60601-1 claimed – | | | | | |
|  |  | | | | | |
| Note – the electrical review will include a review of the document(s) in which conformance with all applicable EN 60601-1 requirements as well as EN 60601-2-x if applicable are tested. Please ensure the tester understands and is familiar with a comprehensive test report/checklist format addressing each applicable requirement. Abbreviated reports and summaries are NOT acceptable. | | | | | |
| 4. | What is the expected Service Life of the device | | | years | | |
| 5. | What is the Essential Performance of the device - | | |  | | |
| 6. | Does the product incorporate Software/Firmware or meets the  Definition of Standalone Software per MEDDEV 2.1/6? | |  | Yes |  | No |
| If “Yes” Have the requirements of EN 62304, including the mandatory risk assessment to EN 14971 been applied in submitted software documents | |  | Yes |  | No |
| Version of Standard : |  | | | | |
| If not the latest version, please explain - |  | | | | |
| **7.** | Please provide the safety classification (A, B, C) and rationale for each software or firmware unit. | | | | | |
|  | Please also provide all documentation to demonstrate compliance with EN 62304: as shown below | | | | | |
| |  |  |  |  | | --- | --- | --- | --- | | **Table 8 – EN 62304 Compliance** | | | | | **EN 62304 requirement** | **Class A** | **Class B** | **Class C** | | 4.3 Software safety classification | X | X | X | | 5.1 Software development plan | X | X | X | | 5.2 Software  requirements | X | X  (incl. RISK CONTROL measures) | X  (incl. RISK CONTROL measures) | | 5.3 Software  ARCHITECTURAL design | N/A | X | X  (incl. segregation for RISK CONTROL) | | 5.4 Software detailed  design | N/A | X | X  (incl. detailed design of SOFTWARE UNIT & interfaces) | | 5.5 SOFTWARE UNIT  implementation | X | X  (incl. verification & acceptance criteria) | X  (incl. verification & acceptance criteria) | | 5.6 Software integration  & integration testing | N/A | X | X | | 5.7 SOFTWARE SYSTEM  testing | N/A | X | X | | 5.8 Software release (VERSION) | X | X  (incl. ANOMALIES, how created, archive, repeatability) | X  (incl. ANOMALIES, how created, archive, repeatability) | | 6.1 Software  maintenance plan | X | X | X | | 6.2 Problem &  modification analysis | X | X  (incl. analysis of CHANGE REQUESTS) | X  (incl. analysis of CHANGE REQUESTS) | | 6.3 Modification  implementation | X | X | X | | 7.1 Analysis of software  contributing to hazardous  situations | N/A | X | X | | 7.2 RISK CONTROL  measures | N/A | X | X | | 7.3 VERIFICATION of RISK CONTROL measures | N/A | X | X | | 7.4 RISK MANAGEMENT of software changes | X | X  (incl. impact on existing RISK CONTROL measures) | X  (incl. impact on existing RISK CONTROL measures) | | 8 Software configuration  Management PROCESS | X | X | X | | 9 Software problem  resolution PROCESS | X | X | X | | | | | | |

| **SECTION 12: MEDICAL ELECTRICAL EQUIPMENT, SYSTEMS & SOFTWARE** | |
| --- | --- |
| 7. | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | Table 9 – Collateral Standards | | | | | | | | | **EN 60601-1-X** | **Year** | **Title** | | **Applied/ Report** | | | | | EN 60601-1-2 |  | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests | |  | Yes |  | No | | Report: | | | | | EN 60601-1-3 |  | Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment | |  | Yes |  | No | | Report: | | | | | EN 60601-1-6 |  | Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability | |  | Yes |  | No | | Report: | | | | | EN 60601-1-8 |  | Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems | |  | Yes |  | No | | Report: | | | | | EN 60601-1-10 |  | Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers | |  | Yes |  | No | | Report: | | | | | EN 60601-1-11 |  | Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment) | |  | Yes |  | No | | Report: | | | | | For Collateral Standards not applied, please explain - | | |  | | | | | |

| **Section 12: Medical Electrical Equipment, Systems & Software** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| 1. | |  |  |  |  | | --- | --- | --- | --- | | **Table 10 – Particular Standards** | | | | | **EN 60601-2-X\*** | **Year** | **Title** | **Report** | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | | \*Also includes EN 80601-2-x.For Particular Standards not applied, please explain - | | | | |  | | | | | | | | | |
| 8. | Does the product incorporate SaMD or COTS | |  | Yes |  | No |
| If “Yes” Have the requirements of FDA Guidance on cybersecurity been applied | |  | Yes |  | No |
| Version of Guidance : |  | | | | |

| SECTION 13: CLINICAL PERFORMANCE | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 13.1 Clinical Evaluation | | | | | | | | | |
| **Revisions to the MDD 93/42/EC by 2007/47/EC have implications for the clinical data & the evaluation of the data to be provided by Manufacturers to the Notified Body, to demonstrate the clinical safety & performance of the medical device.**  **Clinical data must always be documented for all medical device classifications.**  **MedDev 2.7.1 latest version provides guidance on the procedure to be adopted by the Manufacturer to evaluate clinical data.**  **Please supply a Clinical Evaluation Report to support the safe use of the device as per MedDev 2.7.1.** | | | | | | | | | |
| 1. | Please provide the document number and location of the Clinical Evaluation Report (CER) - | | | |  | | | | |
|  | Does the supporting documentation submitted to NSAI include: | | | | | | | | |
|  |  | | Literature search protocol | | | | | | |
|  |  | | Full text of articles referenced in the CER. | | | | | | |
|  | If not please justify: | | | | | | | | |
|  |  | | | | | | | | |
| 2. | Does the CER comply with MedDev 2.7.1 | | | | |  | Yes |  | No |
|  | Version of MedDev used: | | |  | | | | | |
|  | If “No” please justify - | | | | | | | | |
|  |  | | | | | | | | |
| 3. | a. | Does the CER address the relevant risks of predicate device | | | |  | Yes |  | No |
|  |  | If “No” please justify - | | | | | | | |
|  |  |  | | | | | | | |
|  | b. | Does the CER address Post market surveillance and or PMCF ie. Registry or study (reference MED DEV 2.12 /2 ) | | | |  | Yes |  | No |
|  | c. | How often is the CER updated with data from the post market surveillance(reference Annex X 93/42/EEC | | | | | | | |
|  |  | How often is the CER updated? | | | | | | | |
|  |  | Please provide justification for the frequency of update | | | | | | | |
| 4. | Please identify the individual(s) who performed the clinical evaluation - | | | | | | | | |
|  |  | | | | | | | | |
|  | Is their CV included? | | | | |  | Yes |  | No |
|  | Is a declaration of interest of the evaluators included | | | | |  | Yes |  | No |
|  | If “No” please explain - | | | | | | | | |
|  |  | | | | | | | | |
|  | Please provide justification of the choice of evaluator(s) - | | | | | | | | |
|  |  | | | | | | | | |
| 5. | For this device : | | | | | | | | |
|  | a. | Are any further clinical investigations planned | | | |  | Yes |  | No |
|  | b. | Are any further clinical investigations on-going | | | |  | Yes |  | No |
|  | c. | Are any other relevant clinical investigations completed | | | |  | Yes |  | No |
|  | If “Yes” please provide additional information and status – | | | | | | | | |
|  |  | | | | | | | | |
|  | (**note** – not limited to EU S&P studies / Investigations, i.e. include reference to Other Geographical Reg Requirements, studies/investigations for reimbursement purposes, etc) | | | | | | | | |
| 6. | For clinical investigations, does the supporting documentation submitted to NSAI include: | | | | | | | | |
|  |  | Letter of no objection from Competent Authority(s) (CAs) or other regulatory agency(s) as appropriate | | | | | | | |
|  |  | Clinical investigation plan and amendments for which no grounds for objection were raised | | | | | | | |
|  |  | Ethics committee opinion(s) and comments arising from their review | | | | | | | |
|  |  | Signed and dated final report (signed by the sponsor, the co-ordinating clinical investigator – if appointed – and principal investigator at each site). | | | | | | | |
|  | If not please justify - | | | | | | | | |
|  |  | | | | | | | | |