

**Medical Devices**

# Application Form

* **Class 1 Sterile**
* **Class 1 Measuring**
* **Class 1 Sterile & Measuring**

[**Submission**](#aaNSAI_TableOfContents) **Details**

**Please tick all that apply:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Class 1 Sterile | | |  |  |
|  | Class 1 Measuring | | |  |  |
|  | Class 1 Sterile & Measuring | | |  |  |
|  | Transfer (from another NB) | | |  | |  | | --- | |  | |
|  | Fast Track (expedited) | | |  | Modular (partial application) |
|  |  | | |  |  |
|  | | | | | |
| 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 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 the following (Hard copies not required)   NSAI upload facility : see <http://www.nsaiinc.com/>   1. Supporting documents should be in 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 of procedures/simulated use would also be helpful, if available. |

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|  |  |
| --- | --- |
| 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 |
|  | (Draft) Labelling & IFU |
|  | Essential Requirements Checklist |
|  | Performance/Complaint Analysis |
|  | Risk Management documentation |
|  | Sterilisation Validation(s) – if provided sterile |
|  | packaging and device stability data – if necessary |
| **For Transfers** | |
|  | Copy of existing Notified Body Certificate(s) |
|  | Transition Plan |
|  | Contact details for existing Notified Body, including formal permission to contact 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 inform NSAI which issued the EC design-examination certificate of any changes to the approved design, wherever the changes could affect 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 and supply it with all relevant information, in particular:   - 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.   * On receipt of the CE Mark approval from NSAI, it is our intention to commercialise the product. In the event of non-commercialise of the said product we commit to notify NSAI of this decision. * 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 | | | | | | |  | | | | |
| 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 : | | | | | | | |  | | |
| **MDD ONLY:** | | | | | | | | | | | |
| Class | |  | Is |  | Im | | | Rule(s) | | |  |
| Rationale | |  | | | | | | | | | |
| Conformity Assessment | | Annex |  | II |  | | V (+VII) |  | | VI | |
| Full QA | | | Prodn QA | | | Product AQ | | | |
| 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** |
|  |  |  |  |
|  |  |  |  |
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|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

| SECTION 2: DESCRIPTION OF DEVICE |
| --- |
| Please provide a full description of the device which demonstrates that the product is covered under Directive 93/42/EEC: |
| 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: 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. | 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 - | | | | | | | |
|  | | | | | | | |
| 4. | If an IFU is not provided please rationalize how the device can be used safely in the absence of such instructions | | | | | | | |
|  | | | | | | | |

| Section 6: Solutions to Essential Requirementsand Harmonised Standards | | | | | |
| --- | --- | --- | --- | --- | --- |
| 1. | Location of the solutions to Essential Requirements(ER) in the supporting documentation: | | | | |
|  |  | | | | |
| FOR MDD CLASS I STERILE devices: Compliance with ER 8 & 13  FOR MDD CLASS I MEASURING devices: Compliance with ER 10 & 13  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. | 1. Please list the relevant Harmonised standards related to the sterile and measuring function in Table 3 below | | | | |
|  | | **TABLE 3 – Applicable Harmonised Standards List** | | | | --- | --- | --- | | **Standard** | **Year** | **Has the Standard been applied in full**  **Yes / No** | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | | | | | |

| Section 7: 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 8: Risk Management | | | | | |
| --- | --- | --- | --- | --- | --- |
| FOR CLASS I STERILE devices: risks related to sterility  FOR CLASS I MEASURING devices: risks related to measuring function. | | | | | |
| **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 | | | | |
|  | | | | |
| **4.** | 1. Please indicate where in the risk management file the overall residual risk conclusion is located | | | | |
|  | | | | |

| Section 9: Sterilisation | | | | | | | | | | | | | | | | | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 9.1 Sterilisation ValidationFor devices provided sterile | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | 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 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 9: Sterilisation** | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 9.2 Maintenance of Sterility over shelf life | | | | | | | | | |
| Does the product have a shelf life | | | |  | | Yes |  | No | |
| If “no” please justify: | |  | | | | | | | |
| 1. | Please define the shelf life/expiry date | | | | Years | | | |
|  | Please confirm the number of sterilisation cycles that the device and packaging have undergone prior to stability analysis - | | | |  | | | |
| 2. | Please describe the preconditioning applied (eg. Ageing, transport etc): | | | | | | | |
|  |  | | | | | | | |
| 3. | Is compliance with EN ISO 11607 latest version claimed | | |  | | Yes |  | No |
| If “no” please justify: |  | | | | | | |
| 4. | Confirm start date of real time Packaging studies | |  | | | | | |
| 5. | Please list all relevant reports which substantiate Packaging shelf life – | | | | | | | |
|  | | | | | | | |

| Section 10: MEASURING FUNCTION | |
| --- | --- |
| 1. | Describe how the device is designed and manufactured to provided sufficient accuracy and stability within appropriate limits of accuracy |
|  |  |
| 2. | Provide details of the relevant validations |
|  |
| 3. | Define the limits of accuracy |
|  |
| 4. | Describe how the measurement, monitoring and display scale are designed in line with Ergonomic principles |
|  |
| 5. | Describe the units of measure |
|  |