|  |
| --- |
| **If you have completed CE Product Significant Change: Notification and Review: MTF-1023 form then only complete the Red Tick box** ☒ **form requirements detailed in Section 8: Significant Change Assessment.**Ensure the NSAI completed **CE Product Significant Change: Notification and Review: MTF-1023** form is submitted with this application.Please complete the **CE Product Significant Change: Notification and Review: MTF-1023** form if you are unsure if your proposed change is a significant change under the MDD/AIMD *or* if this proposed change will require submission of a new application under the MDR. The form can be found on the website [<here>](https://www.nsai.ie/certification/medical-devices/ce-marking-for-medical-devices/).  |



**Medical Devices**

**Significant Change Application Form**

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

**Submission Details**

**Please tick all that apply:**

|  |  |  |  |
| --- | --- | --- | --- |
| [ ]  | Class 1 Sterile |  |  |
| [ ]  | Class 1 Measuring |  |  |
| [ ]  | Class 1 Sterile & Measuring |  |  |
| PO Number |       |
| **Directive(s) that apply:** | **NSAI File Number** |
| [ ]  | MDD (93/42/EEC)  | 252.     /      |

|  |  |
| --- | --- |
| Proposed Significant Change Reference Number as per MTF-1023, if relevant. |  |

|  |
| --- |
| 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 one of 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 any 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 & device Stability data  |

| 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 (e.g., MIR, FSCA, FSN, etc.) 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 and 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 applicable)* |       |
| **Sterilisation Site(s):** *(if applicable)* |       |
| **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 and 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 QA** |
| **Date of this application***(i.e., date of Declaration of Applicant):* |       |

| Section 2: Nature of the Change |
| --- |
| **1.** | Please provide a clear, detailed description of the change(s): |
|       |
| **2.** | Did the change(s) arise from a vigilance or performance issue | **[ ]**  | **Yes** | **[ ]**  | **No** |
| If “Yes” – please advise:  |       |
| **3.** | Has NSAI received the Vigilance Report(s) | **[ ]**  | **Yes** | **[ ]**  | **No** |
| If “Yes” – please advise:  |       |
| If “No” please: |
| **a.** | Justify:  |       |
| **b.** | If applicable, please submit a copy of the Competent Authority report(s) along with the completed NSAI Vigilance Form located at [<http://www.nsaiinc.com/services/MedicalDevice> -“Vigilance Reporting”] to vigilance@nsai.ie |
| **4.** | Has this product been the subject of product recalls or Incident Reports in other Regulatory geographies outside EU? If yes, please summarize and provide details with supporting documentation. |
|       |
| **5.** | For those failure modes associated with the identified Root Causes, please clarify if the Occurrence Rates outlined in the Risk Management File required an update based on the observed real-world rates. |
|       |

| Section 3: Intended Use of the Device |
| --- |
| **1.** | Is there a change in Intended Use | **[ ]**  | **Yes** | **[ ]**  | **No** |
| **2.** | Please enter a full description of the revised intended use and/or indications for use of the device: |
|       |
| **3.** | Does this change impact the classification rule: | **[ ]**  | **Yes** | **[ ]**  | **No** |
| If “No” please justify: |       |

| Section 4: Labelling and IFU |
| --- |
| **Please select NA if this section is not required for the significant change.** | [ ]  N/A |
| **1.** | Is there a change to the Labelling/IFU | **[ ]**  | **Yes** | **[ ]**  | **No** |
| **Please supply a sample of the revised draft labelling & IFU in English** |
| **2.** | Location of the sample Label(s) & IFU in the supporting documentation      |
| **3.** | Please clarify the exact nature of change(s) to the labelling/IFU based on the proposed change(s) under review:      |
| **4.** | Are the requirements of EN 980 & EN 1041 being met | **[ ]**  | **Yes** | **[ ]**  | **No** |
| Version of Standard: |       |

| Section 5: Solutions to Essential Requirements and Harmonised Standards |
| --- |
| **Please select NA if this section is not required for the significant change.** | [ ]  N/A |
| **Please indicate how relevant Essential Requirements (Annex I) of the Directive are met for the proposed changes.** |
| **1.** | Location of the revised solutions to Essential Requirements in the supporting documentation |
| FOR CLASS I STERILE devices: In particular ER 8      |
| FOR CLASS I MEASURING devices: In particular ER 10      |
| **2.** | Please list the relevant revised/updated Harmonised Standards in Table 2 below |
|

| **TABLE 2 – Applicable Harmonised Standards List** |
| --- |
| **Standard** | **Year** | **Has the Standard been applied in full [Yes / No]** |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |

 |

| Section 6: Risk Management |
| --- |
| **1.** | Did the proposed change affect or change any existing risks | **[ ]**  | **Yes** | **[ ]**  | **No** |
| If “no” please justify: |       |
| **2.** | Did the proposed change introduce any new risks | **[ ]**  | **Yes** | **[ ]**  | **No** |
| If “no” please justify: |       |
| **3.** | Was the Risk documented? (e.g., during change control process, update to FMEA, memo to file etc.) | **[ ]**  | **Yes** | **[ ]**  | **No** |
| If “no” please justify: |       |
| **4.** | If no update to Risk Management File, please provide rationale: |
|       |

| Section 7: Sterilisation |
| --- |
| **Please select NA if this section is not required for the significant change.** | [ ]  N/A |
| 7.1 Sterilisation |
| **1.** | Does the proposed change affect sterilisation | **[ ]**  | **Yes** | **[ ]**  | **No** |
| If “no” please justify: |       |
| **2.** | Is a full validation/revalidation required | **[ ]**  | **Yes** | **[ ]**  | **No** |
| **3.** | If a full validation/revalidation is not completed, please provide an Adoption Justification / Rationale Report - |
|

| **Table 3 – Sterilisation Information Summary for Changes** |
| --- |
| **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 7: Sterilisation |
| --- |
| 7.2 Maintenance of Sterility over shelf life |
| Does the change affect the products shelf life | **[ ]**  | **Yes** | **[ ]**  | **No** |
| If “no” please justify: |       |
| **1.** | Please define the shelf life/expiry date |       Years |
| **2.** | Is the aging based on  | [ ]  | Accelerated | [ ]  | Real Time Data |
| **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 to justify the proposed change:1.
 |
| Protocol #     Report #       |

| Section 8: Measuring Function |
| --- |
| **Please select NA if this section is not required for the significant change.** | [ ]  N/A |
| **1.** | Does the proposed change affect the measuring function | **[ ]**  | **Yes** | **[ ]**  | **No** |
| If “no” please justify: |       |
| **2.** | If yes provide copies of the updated validations:      |