**Please note**

In accordance with MDR And IVDR, Annex IX, 2.4 the manufacturer 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.

The notified body shall assess the changes proposed, determine the need for additional audits and verify whether after those changes the quality management system still meets the requirements.

This form facilitates these requirements. Please complete sections **1 to 3** inclusive and follow the submission instructions below section 3.

**Fees**

A fee of €500 / $600 be applied to all submissions of this form for substantial change notification assessment.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**1. General Information**

|  |  |  |  |
| --- | --- | --- | --- |
| **General Information** | | | |
| PO Number: |  | | |
| Date (DD-Mmm-YYYY) |  | | |
| Manufacturer: |  | | |
| Manufacturer Address: |  | | |
| NSAI MDR/IVDR File Number: | 745.XXXX  746.XXXX | Product Cert Expiry | DD-Mmm-YYYY |
| Product Name/Generic Device Group: |  | | |
| Company Liaison and Details: | Name:  Address:  Email:  Telephone: | | |

**2. Proposed Change Category**

|  |  |
| --- | --- |
| **Please tick the appropriate change category; multiple may be selected.**  ***Note: This is not an exhaustive list*** | |
| Proposed change to: | |
|  | the intended purpose |
|  | the design |
|  | the device performance |
|  | the device specifications |
|  | the software |
|  | a material |
|  | terminal sterilisation method |
|  | device packaging |
|  | company Name/Brand name/Product Family |
|  | a relocation/address change |
|  | Other  *Note: details will be requested below* |

**3. Description of Proposed Change**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Approved Device Seeking Substantial Change**  ***Note:* this is the device/family currently approved by NSAI.** | | | | | | |
| Applicable Regulation: | MDR | | | | | |
| Class I sterile | | Class I measuring | | Class I Reusable SI | | |
| Class IIa | | Class IIb Non-Implantable | | Class III/IIb Implantable | | |
| Applicable Regulation: | IVDR | | | | | |
| Class A | Class B | | Class C | | Class D | |
| Approved Device/Generic Device Group Description and Intended Purpose: | | | | | | |
|  | | | | | | |
| **Detailed Description of Proposed Change**  ***Note:* The description must be contained and communicated within the box provided below. Pictures and tables can be inserted below.** | | | | | | |
| Please provide as much detail as possible: | | | | | | |
| **Why is this change being made** | | | | | | |
| Please provide as much detail as possible: | | | | | | |
| **Projected Timeline** | | | | | | N/A |
| Please detail any time sensitive issues if applicable: | | | | | | |

|  |
| --- |
| Please submit this form **only as a word document** to [substantial.change@nsai.ie](mailto:substantial.change@nsai.ie).  The proposed change will now go to an NSAI committee where section 4 will be completed.  The response, Section 5, and options for progression will be communicated to you shortly. |

**4. Substantial Change Assessment**

|  |  |  |
| --- | --- | --- |
| **For NSAI Use Only** | | |
| Assessment date: | |  |
| Assessment performed by: | |  |
| Proposed Change Reference Number: | |  |
| Proposed change to: | | |
|  | the intended purpose | |
|  | the design | |
|  | the device performance | |
|  | the device specifications | |
|  | the software | |
|  | a material | |
|  | terminal sterilisation method | |
|  | device packaging | |
|  | company Name/Brand name/Product Family | |
|  | a Relocation/address change | |
|  | Other | |
| Assessment of proposed change:  Based on the review of the provided information… | | |
| Guidance/reference document/standard utilized for assessment: | | |
|  | | |
|  | **Option 1:** The proposed change is **not** a substantial change that requires submission to NSAI.  No further action is required of the client. | |
|  | **Option 2:** The proposed change **is** a substantial change under the MDR/IVDR that requires submission to NSAI. | |
|  | **Option 3:** The proposed change will require a **new** conformity assessment.  A new application under the MDR/IVDR is required. | |

**5. Formal Response of Assessment**

|  |  |
| --- | --- |
| **NSAI Formal Response** | |
|  | Submission of Product Substantial Change to NSAI under MDR/IVDR is **not** Required. |
| Following review, the proposed change under the MDR/IVDR does not require submission to NSAI.  Please retain this for your records.  **No further action is required.** | |

|  |  |
| --- | --- |
| **NSAI Formal Response** | |
|  | Only a **QMS** Substantial Change is Required. |
| The change has been determined as a QMS substantial change only.  Please **complete QMS Substantial Change form on the website or located** <[here>.](https://www.nsaiinc.com/services/medicaldevice/iso-13485/) | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **NSAI Formal Response** | | | | | | |
|  | Submission of Product Substantial Change to NSAI under MDR/IVDR **is Required.** | | | | | |
| Please download the below specified class specific form on the NSAI website [here](https://www.nsai.ie/certification/medical-devices/ce-marking-for-medical-devices/)  **NOTE – You must** contact Gwen Thornberry at [Gwen.Thornberry@nsai.ie](mailto:Gwen.Thornberry@nsai.ie) to schedule a significant change review date prior to submission of completed form.  Include **a copy of this form** with the submission for traceability. | | | | | | |
| Device Classification: | | | MDR | | | |
| Class I S-M-RSI | | | Class IIa IIb Non-Implantable | | Class III/IIb Implantable | |
|  | | | | | | |
| Device Classification: | | | IVDR | | | |
| Class A | | | Class B | Class C | | Class D |
| **Days** | | **Estimate of number of review days based on nature of change.**  **Billing is at standard product review day rate**  *(Calculated based on information available at time of this disposition – actual time may vary based on quality of data submitted and alignment with proposed change discussed)* | | | | |
|  | **QMS** Substantial Change is **also** Required. | | | | | |
| Please also complete QMS Substantial Change form on the NSAI website or located <[here](https://www.nsaiinc.com/services/medicaldevice/iso-13485/)>. | | | | | | |

|  |  |
| --- | --- |
| **NSAI Formal Response** | |
|  | Submission of a **new** conformity assessment application to NSAI under MDR/IVDR is Required.  Please contact Gwen at [Gwen.Thornberry@nsai.ie](mailto:Gwen.Thornberry@nsai.ie) to schedule a new conformity assessment submission. |
|  | **QMS** Substantial Change is **also** Required. |
| Please also complete QMS Substantial Change form on the NSAI website or located <[here](https://www.nsaiinc.com/services/medicaldevice/iso-13485/)>. | |

**End of Form**