**Please note**

That this is an optional ***assessment*** form to determine if your proposed change is a substantial change under the MDD/AIMD ***or*** if this proposed change will require submission of a new application under the MDR.

**Before you begin**

Carefully read points **1**, **2, 3** and **4** below.

**1. Ensure:**

That your proposed change has been **assessed and documented** within your **internal change control process,** including consideration of the potential impact on an open MDR application

**2. Do NOT complete**

This form if your proposed change is one of the following:

|  |  |
| --- | --- |
| A substantial change to design or intended purpose for a class III/IIb implantable device. | This requires an application under MDR 2017/745, to schedule a new MDR application please contact [substantial.change@nsai.ie](mailto:substantial.change@nsai.ie) ***and*** [Gwen.Thornberry@nsai.ie](mailto:Gwen.Thornberry@nsai.ie) |
| A substantial change that is **not a design or intended purpose** change as per MDD/AIMD and or NBOG BPG 2014-3. | To schedule a substantial change under the MDD please contact [substantial.change@nsai.ie](mailto:substantial.change@nsai.ie) ***and*** [Gwen.Thornberry@nsai.ie](mailto:Gwen.Thornberry@nsai.ie)  Other Substantial change examples include, but are not limited to:   * EU Authorised Rep * New Sterilisation Site * Change to Certificate details |

***Note:* Amended MDD/AIMD certificates cannot be issued following MDR 2017/745 date of application (26th May 2021). This will require an application to the MDR, please contact your CSR to schedule a new MDR application.**

**3. Complete this Form and Submit if you are:**

* unsure if your proposed change meets the minimum requirements for a substantial change under the MDD/AIMD.
* unclear as to whether your change is substantial and may trigger an application for MDR 2017/745.

**4. Fees**

A fee of €500/$650 will be applied to all submissions of this form for substantial change notification assessment.

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

Following point 4 Please complete sections **5 to 7** inclusive and submit the below form.

**5. General Information**

|  |  |  |  |
| --- | --- | --- | --- |
| **General Information** | | | |
| PO Number: |  | | |
| Date (DD-MON-YYYY) |  | | |
| Company/Division/Business Unit: |  | | |
| Manufacturer Address: |  | | |
| NSAI MDD File Number: | 252.XXXX  253.XXXX | MDD Product Cert Expiry | DD-MON-YYYY |
| Product Name/Family: |  | | |
| Company Liaison and Details: | Name:  Address:  Email:  Telephone: | | |

**6. 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* |

**7. Description of Proposed Change**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Approved Device Seeking Substantial Change**  ***Note:* this is the device/family currently approved by NSAI.** | | | | |
| Device Class | Class I s | Class I m | Class IIa | |
| IIb **non**-implantable | IIb Implantable | Class III | |
| AIMD |  | | |
| Approved Device/Family Description and Intended Use: | | | | |
|  | | | | |
| **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 but no additional files are to be supplied/attached.** | | | | |
| Please provide as much detail as possible and ensure to include justification/rationale with regard to impact/no impact: | | | | |
| **Why is this change being made** | | | | |
| Please provide as much detail as possible: | | | | |
| **Projected Timeline:** | | | | NA |
| 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 8 will be completed.  The response, Section 9, and options for progression will be communicated to you shortly. |

**8. Substantial Change Assessment**

|  |  |  |
| --- | --- | --- |
| **For NSAI Use Only** | | |
| Assessment date: | |  |
| Assessment performed by: | |  |
| 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… | | |
|  | MDCG 2020-3: | |
|  | NBOG BPG 2014-3: | |
|  | **Option 1:** The proposed changeIs **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 MDD that requires submission to NSAI. | |
|  | **Option 3:** The proposed change **Is** a substantial change as per MDR Article 120, section 3. Therefore, change cannot be made under the MDD.  A new application under the MDR is required. | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Substantial Change Requirements** | | | | |
| Device Class | | Class I s/m |  | |
|  | Section 1: Manufacturer and Product Details  Section 2: Nature of the Change  Section 3: Intended Use of the device  Section 6: Risk Management | | | **Note:** These sections **must be completed** for all MDD substantial Changes. |
|  | Section 4: Labelling and IFU | | | |
|  | Section 5: Solutions to Essential requirements and harmonised Standards | | | |
|  | Section 7: Sterilisation | | | |
|  | Section 8: Measuring function | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Substantial Change Requirements** | | | | |
| Device Class | | Class IIa, IIb Non-Implantable Form requirements | |  |
|  | Section 1: Manufacturer and Product Details  Section 2: Nature of the Change  Section 3: Intended Use of the device  Section 7: Performance and Complaints  Section 8: Risk Management | | **Note:** These sections **must be completed** for all MDD substantial Changes. | |
|  | Section 4: Labelling and IFU | | | |
|  | Section 5: Design and Manufacturing Overview | | | |
|  | Section 6: Solutions to Essential Requirements and Harmonised | | | |
|  | Section 9: Sterilisation & Stability | | | |
|  | Section 10: Biocompatibility | | | |
|  | Section 11: Medical Electrical Equipment Systems & Software | | | |
|  | Section 12: Clinical Performance (human) | | | |

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| **Substantial Change Requirements** | | | | |
| Device Class | | Class III/IIb Implantable Form requirements | |  |
|  | Section 1: Manufacturer and Product Details  Section 2: Nature of the Change  Section 3: Intended Use of the device  Section 6: Risk Management | | **Note:** These sections **must be completed** for all MDD substantial Changes. | |
|  | Section 4: Labelling and IFU | | | |
|  | Section 5: Solutions to Essential Requirements and Harmonised | | | |
|  | Section 7: Sterilisation | | | |
|  | Section 8: Biocompatibility | | | |
|  | Section 9: Medical Electrical Equipment Systems & Software | | | |
|  | Section 10: Device Testing | | | |
|  | Section 11: Clinical Testing (animal model) | | | |
|  | Section 12: Clinical Performance (human) | | | |
|  | Section 15: Critical Process Changes | | | |

**9. Formal Response of Assessment**

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

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **NSAI Formal Response** | | | | | |
|  | Submission of Product Substantial Change to NSAI under MDD **is Required.** | | | | |
|  | Class I s/m form |  | Class IIa, IIb Non-Implantable |  | Class III/IIb Implantable |
| Please download the following selected form [<here>](https://www.nsai.ie/certification/medical-devices/ce-marking-for-medical-devices/) or from the NSAI website.  Once downloaded **only complete** the Red Tick box  form requirements detailed above in **Section 8 Substantial Change Assessment.**  **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. | | | | | |
|  | **QMS** Substantial Change is **also** Required. | | | | |
| Please complete QMS Substantial Change form located <[here](https://www.nsaiinc.com/services/medicaldevice/iso-13485/)>. | | | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **NSAI Formal Response** | | | | | |
|  | Submission of Product Substantial Change only to NSAI under MDD **is Required.** | | | | |
|  | Class I s/m form |  | Class IIa, IIb Non-Implantable |  | Class III/IIb Implantable |
| Please download the following selected form [<here>](https://www.nsai.ie/certification/medical-devices/ce-marking-for-medical-devices/) or from the NSAI website.  Once downloaded **only complete** the Red Tick box  form requirements detailed above in **Section 8 Substantial Change Assessment.**  **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. | | | | | |

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| **NSAI Formal Response** | |
|  | An application to **MDR 2017/745** is required. |
| Following review, the proposed change cannot be facilitated under the MDD and requires the submission of a new product application under MDR 2017/745.  To begin this process please complete our RFQ form [<here>](https://www.nsai.ie/certification/medical-devices/iso-13485-management-system-for-medical-devices/).  If already completed, please contact Gwen at [Gwen.Thornberry@nsai.ie](mailto:Gwen.Thornberry@nsai.ie) to schedule your MDR review.  The MDR Product Form Packs can be downloaded [<here>](https://www.nsai.ie/certification/medical-devices/ce-marking-for-medical-devices/). | |