**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 ***and*** 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 ***and*** Gwen.Thornberry@nsai.ieOther 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/$600 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-Mmm-YYYY) |  |
| Company/Division/Business Unit: |  |
| Manufacturer Address: |  |
| NSAI MDD File Number: | 252.XXXX253.XXXX | MDD Product Cert Expiry | DD-Mmm-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: |

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| --- |
| Please submit this form **only as a word document** to 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. |

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| **Substantial Change Requirements** |
| Device Class | [ ]  Class I s/m |
| [ ]  | Section 1: Manufacturer and Product DetailsSection 2: Nature of the ChangeSection 3: Intended Use of the deviceSection 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 |

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| **Substantial Change Requirements** |
| Device Class | [ ]  Class IIa, IIb Non-Implantable Form requirements |
| [ ]  | Section 1: Manufacturer and Product DetailsSection 2: Nature of the ChangeSection 3: Intended Use of the deviceSection 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 DetailsSection 2: Nature of the ChangeSection 3: Intended Use of the deviceSection 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**

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| **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/) |

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| **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 [x]  form requirements detailed above in **Section 8 Substantial Change Assessment.****NOTE – You must** contact Gwen Thornberry at 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/)>. |

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| **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 [x]  form requirements detailed above in **Section 8 Substantial Change Assessment.****NOTE – You must** contact Gwen Thornberry at 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 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/). |

**End of Form**