**Before you begin**

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

Only **one** substantial change should be submitted on this form. If you have more than one change to report, please use separate forms for each change.

1. **Ensure:**

That your proposed change has been **assessed and documented** within your **internal change control process,** including consideration of the potential impact on any ongoing change notifications.

Before submission, please ensure that page 2 has been signed by an authorised company representative.

1. **Do NOT complete**
* This form if you have an ongoing assessment of the Technical Documentation for the related product. NSAI do not accept changes to files/products that are already submitted for Technical Documentation assessment (and have not yet been approved).

In this situation, a Change Notification shall be submitted by the client after the ongoing Technical Documentation assessment has been completed.

* This form if your proposed change is a clear significant change to design and/or intended purpose for a device certified under MDD/AIMD/IVDD. (See following guidance: NBOG BPG 2014-3, MDCG 2020-3, MDCG 2022-6). Such changes require an application under MDR 2017/745 or IVDR 2017/746.

To apply for MDR/IVDR please contact NSAI at medicaldevices@nsai.ie

**Note*:* Updated MDD/AIMD certificates cannot be issued following MDR 2017/745 date of application.**
**Updated IVDD certificates cannot be issued following IVDR 2017/746 date of application.**

1. **Fees**

A fee of €685/$755 per hour will be applied to all submissions of this form for substantial change notification assessment.

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

1. **General Information**

|  |  |
| --- | --- |
| PO Number (if required for invoicing): |  |
| Date (DD-Mmm-YYYY) |  |
| Company/Division/Business Unit: |  |
| Manufacturer Address: |  |
| NSAI Certificate Number(s):(Always include your MD19.xxxx number and if applicable the “regulatory cert” ID e.g. “745.XXX” or “252.XXX” |  | NSAI Cert Expiry | DD-Mmm-YYYY |
| Company Liaison and Details:  | Name:Email:Telephone: |

|  |
| --- |
| **Signature** |
| I / We declare the information in this form is correct and has been submitted as instructed. Information not provided, or provided in the wrong format, may result in prolonged review time, delays, or termination of review.I / We acknowledge and accept that for changes in ownership, name, new facilities, etc.,MCN-1001 Client Contract Schedule 1, MCN-1002 Client Contract Schedule 2 and Client Agreements are maintained and continue to apply. |
| Signed on Behalf of the Applicant |
| **Please****Sign****Here** | u |  |
| **Print Name** |  |
| **Position / Title:** |  |

**5. Proposed Change Category**

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| --- |
| **Please tick the appropriate change category; multiple may be selected.*****Note: This is not an exhaustive list*** |
| **Device** |
| [ ]  | Device portfolio - **addition** of productsA new and COMPLETE MTF-3015 (MDR) or MTF-4002 (IVDR) must be submitted with this Change Notice – Downloadable from NSAI web. [Documents for download](https://www.nsai.ie/certification/medical-devices/ce-marking-for-medical-devices/) |
| [ ]  | Device portfolio - **removal** of productsA new and COMPLETE MTF-3015 (MDR) or MTF-4002 (IVDR) must be submitted with this Change Notice – Downloadable from NSAI web. [Documents for download](https://www.nsai.ie/certification/medical-devices/ce-marking-for-medical-devices/) |
| [ ]  | The device intended purpose |
| [ ]  | The device design |
| [ ]  | The device performance or conditions prescribed for use of the device |
| [ ]  | The device specifications, including manufacturing specifications |
| [ ]  | The device software |
| [ ]  | A material |
| [ ]  | Terminal sterilisation method |
| [ ]  | Device packaging |
| [ ]  | Product name /Company Name /Brand name |
| [ ]   | An ancillary medicinal substance incorporated into a device\* |
| [ ]  | Changes in the epidemiological context, for example, a new strain of infectious agent that impacts IVD device classification |
|[ ]  Changes that could affect compliance with the CS or with other solutions chosen by the manufacturer which were approved through the EU technical documentation assessment certificate |
| [ ]  | Article 117 Variation (within the current device) |
| [ ]  | Article 117 Additional Marketing Authorization |
| [ ]  | Other :  |

*\* Note – even if the proposed change is not a direct change to the ancillary medicinal substance or its manufacture, NSAI must consult the relevant medicines competent authority to confirm that, given the specific nature of the proposed change, the quality and safety of the ancillary substance does not need to be re-evaluated by the relevant medicine’s competent authority.*

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| **Please tick the appropriate change category; multiple may be selected.*****Note: This is not an exhaustive list*** |
| **QMS** |
| [ ]  | New Ownership  |
| [ ]  | New Company Name*Please provide a signed official document stating the new company name.* |
| [ ]  | Change to scope of existing certification (registration)  |
| [ ]  | Change in Management Representative / NSAI Contact |
| [ ]  | Changes to Quality Manual |
| [ ]  | Change in Critical Supplier(s) |
| [ ]  | Change in employee number (FTE) |
| [ ]  | Addition or reduction in Facilities[ ]  Relocation of Design or Production activities[ ]  Add a New Location/Site[ ]  Expansion of existing Facility[ ]  Elimination of existing Facility |
| [ ]  | MDSAP only: addition/deletion of jurisdiction |
| [ ]  | Withdrawal of certification |
| [ ]  | Transfer of certification (to another Notified / Certification Body)[ ]  CE – Cert Number: [ ]  QMS (ISO 13485) – Cert Number:  |
| [ ]  | Other: |

**6. Description of Proposed Change**

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| --- |
| **Detailed Description of Proposed Change*****Note:* The description must be contained and communicated within the box provided below.**  |
| [ ]  MDR/IVDR Annex IX Chapter I and III[ ]  MDR /IVDR Annex IX Chapter II[ ]  MDR Annex XI Part A[ ]  MDR Article 117[ ]  MDD Annex II | [ ]  MDD Annex V[ ]  IVDD Annex II[ ]  MDSAP[ ]  No regulation (ISO 13485 only) |
| [ ] ☐ Class I sterile | [ ]  Class I measuring | [ ]  Class I Reusable SI |
| [ ]  Class IIa | [ ]  Class IIb Non-Implantable | [ ]  Class III/IIb Implantable |
| [ ]  List A | [ ]  List B | [ ]  Self-Test |
| [ ]  Class A sterile | [ ]  Class B | [ ]  Class C | [ ]  Class D | [ ]  Self-Test |
| **Description of Change** |
| 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 be reviewed, and the outcome will be communicated to you shortly. |

|  |
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| **For Completion by NSAI** |

**7. Substantial Change Assessment & Response**

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| --- | --- |
| Assessment date: |  |
| Assessment performed by: |  |
| Change Reference Number: |  |

**7.1 Record of communications**

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**7.2 Technical File (device change)**

|  |  |
| --- | --- |
| [ ]  | N/A |
| Assessment of proposed change:Based on the review of the provided information: |
| Guidance/reference document/standard utilized for assessment: |
| [ ]  | MDCG 2020-3:  |
| [ ]  | NBOG BPG 2014-3:  |
| [ ]  | MDCG 2022-6:  |
| [ ]  | Other:  |
| [ ]  | **MDD / IVDD Option 1:** The proposed change **Is Not** a significant change that requires further submission to NSAI.No further action is required of the manufacturer. |
| [ ]   | **MDD / IVDD Option 2:** The proposed change **Is** a significant change under the MDD/IVDD. Submission of further documentation to NSAI is required, see **Table 1.** |
| [ ]  | **MDD / IVDD Option 3:** The proposed change **Is** a significant change **per MDR Article 120 / IVDR Article 110, section 3.** Therefore, change cannot be made under the Directive MDD/IVDD.A new application under the REGULATION (MDR/IVDR) is required. |
| [ ]   | **MDR / IVDR Option 1:** The proposed change **Is Not** a substantial change that requires further submission to NSAI.No further action is required of the manufacturer. |
| [ ]  | **MDR / IVDR Option 1A:** The proposed change **Is** a substantial change. NSAI are aware and will act on the submitted information.No further action is required of the manufacturer.[ ]  *An updated certificate will be issued.* |
| [ ]   | **MDR / IVDR Option 2:** The proposed change **Is** a substantial change under the current scope of MDR/IVDR that requires submission to NSAI (under sampling) in the future. No further action is required of the client at this time.[ ]  *An updated certificate will be issued.* |
| [ ]  | **MDR / IVDR Option 2A:** The proposed change **Is** a substantial change under the regulation.Submission of further documentation to NSAI is required, see **Table 1.***The output of the assessment of the further documentation will be reported separately.*[ ]  *An updated certificate will be issued.* |
| [x]  | **MDR / IVDR Option 2B:** The proposed change **Is** a substantial change which falls under the current certification scope of MDR/IVDR regulation that needs pre-approval and updated EU technical documentation assessment certificates.MDR Submission of further substantial change data is required using form [MDR-3004](https://www.nsai.ie/certification/medical-devices/ce-marking-for-medical-devices/)IVDR Submission of further substantial change data is required using form [[IVDR-1003](https://www.nsai.ie/certification/medical-devices/ce-marking-for-medical-devices/)](https://www.nsai.ie/certification/medical-devices/ce-marking-for-medical-devices/)*The output of the assessment of the further documentation will be reported separately.*[x]  *An updated certificate will be issued.* |
| [ ]  | **MDR / IVDR Option 3:** The proposed change does not fall within the current scope of registration. A **new Technical File submission** under the MDR/IVDR is required. Please download and return the [TD Assessment Pack](https://www.nsai.ie/certification/medical-devices/ce-marking-for-medical-devices/) for completion.*The output of the assessment of the further documentation will be reported separately.*[ ]  *An updated certificate will be issued.* |
| [ ]  | **MDR / IVDR / NBOp Option 4:** Other, as specified below. |

**Table 1:**

|  |
| --- |
| **Substantial Change Further Information Needed:** |
| [ ]  | Manufacturing Details: |
| [ ]  | Nature of the Change (the complete internal change documentation): |
| [ ]  | Intended Use of the device: |
| [ ]  | Risk Management: |
| [ ]   | Labelling and IFU: |
| [ ]   | Solutions to GSPR and/or Harmonised Standards: |
| [ ]   | Sterilisation:  |
| [ ]   | Biocompatibility: |
| [ ]  | Stability: |
| [ ]   | Medical Electrical Equipment Systems: |
| [ ]  | Software: |
| [ ]   | Device Testing: |
| [ ]  | Validation: |
| [ ]  | Quality plan: |
| [ ]  | QMS documentation: |
| [ ]  | Other: |

**7.3 QMS**

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| [ ]  | N/A |
| Assessment of proposed change:Based on the review of the provided information: |
| [ ]  | The proposed change **Is Not** considered to be a substantial change.No further action is required of the manufacturer. |
| [ ]  | The proposed change **Is** considered to be a substantial change.Change acknowledged.No further action is required of the manufacturer. |
| [ ]  | Special Assessment and Verification Required*Audit Duration -**Rationale -**Your Client Service Representative will contact you to schedule the assessment* |
| [ ]  | The change will be reviewed and verified during the next scheduled audit. |
| [ ]  | Updated certificate will be issued. |
| [ ]  | Other:  |

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| **NSAI Signature** |
| NSAI has assessed the change, and our response is documented above. |
| Signed on Behalf of the Notified Body |
|  |