**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 two separate forms.

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. .

1. **Do NOT complete**

This form if your proposed change is:

|  |  |
| --- | --- |
| A clear substantial change to design and/or intended purpose for a device certified under MDD/AIMD/IVDD.(See following guidance: NBOG BPG 2014-3MDCG 2020-3MDCG 2022-6) | Changes to design and / or intended purpose 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.**

**3. Fees**

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

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1. **General Information**

|  |  |
| --- | --- |
| PO Number (if required for invoicing): |  |
| Date (DD-Mmm-YYYY) |  |
| Company/Division/Business Unit: |  |
| Manufacturer Address: |  |
| NSAI Certificate Number: |  | NSAI Cert Expiry | DD-Mmm-YYYY |
| Company Liaison and Details:  | Name:Email:Telephone: |

**5. Proposed Change Category**

|  |
| --- |
| **Please tick the appropriate change category; multiple may be selected.*****Note: This is not an exhaustive list*** |
| **Device** |
| Proposed change to: |
| [ ]  | Device portfolio - **addition** of productsA new and COMPLETE MTF-3015 must be submitted with this Change Notice – Downloadable from NSAI web.  |
| [ ]  | Device portfolio - **removal** of productsA new and COMPLETE MTF-3015 must be submitted with this Change Notice – Downloadable from NSAI web. |
| [ ]  | The device intended purpose |
| [ ]  | The device design |
| [ ]  | The device performance |
| [ ]  | The device specifications, including manufacturing specifications |
| [ ]  | The device software |
| [ ]  | A material |
| [ ]  | Terminal sterilisation method |
| [ ]  | Device packaging |
| [ ]  | Company Name/Brand name |
| [ ]  | A relocation/address change |
| [ ]  | Product name |
| [ ]   | An ancillary medicinal substance incorporated into a device\* |
| [ ]  | Obtained information about changes to the pathogen and markers of infections to be tested, in particular as a consequence of biological complexity and variability i.e. information that could change the performance of the IVD |
| [ ]  | WithdrawalState reason : |

*\* 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** |
| Proposed change to: |
| [ ]  | New Ownership  |
| [ ]  | New Company Name |
| [ ]  | Change to scope of existing registration  |
| [ ]  | Change to scope of existing 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: |

**Note: details will be requested below**

**6. Description of Proposed Change**

|  |
| --- |
| **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.** |
| Applicable Regulation: | [ ]  N/A | [ ]  MDD/AIMD | [ ]  IVDD | [ ]  MDR  | [ ]  IVDR |
| [ ]  Class I sterile | [ ]  Class I measuring | [ ]  Class I Reusable SI |
| [ ]  Class IIa | [ ]  Class IIb Non-Implantable | [ ]  Class III/IIb Implantable |
| [ ]  Class A | [ ]  Class B | [ ]  Class C | [ ]  Class D |
| **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: |

|  |
| --- |
| 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**

|  |  |
| --- | --- |
| Assessment date: |  |
| Assessment performed by: |  |
| Change to Directive certificate products: | Y/N |
| 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 substantial change that requires further submission to NSAI.No further action is required of the manufacturer. |
| [ ]   | **MDD / IVDD Option 2:** The proposed change **Is** a substantial 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 substantial 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 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 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.** |
| [ ]  | **MDR / IVDR Option 2B:** The proposed change **Is** a substantial change which falls under the current certification scope of MDR/IVDR regulation.Submission of substantial change is required using form [MDR-3004](https://www.nsai.ie/certification/medical-devices/ce-marking-for-medical-devices/) |
| [ ]  | **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. |

**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 Essential Requirements and 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… |
| Guidance/reference document/standard utilized for assessment: |
| [ ]  | NBOG BPG 2014-3:  |
| [ ]  | Other:  |
| [ ]  | The proposed change **Is Not** considered to be a substantial change.No further action is required of the manufacturer. |
| [ ]  | 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  |