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| **IVDR 2017/746**  **Substantial Change Product Application Form** |

# **Section 1**

**Administration**

|  |  |  |
| --- | --- | --- |
| **General Information** | | |
| PO Number: | |  |
| Manufacturer  (as per definition within the regulation): | |  |
| Address: | |  |
| Device or Device Group Name: | |  |
| Classification: | |  |
| SRN: | |  |
| EU Authorised Representative: | ☐ NA | Name:  Address:  Email:  Telephone: |
| Name of Person Responsible for Regulatory Compliance: | |  |
| Company Liaison and Details: | | Name:  Address:  Email:  Telephone: |

|  |  |  |  |
| --- | --- | --- | --- |
| **Please Complete for Impartiality Review** | | | |
| **Critical Suppliers Of Products And Services as defined by your purchasing process for**  **the medical device under review**  ***Note*: A critical supplier is a supplier delivering materials, components, or services that may influence the safety and performance of the device \*NBOG BPG 2010-1.** | | | |
| **Product/Service** | **Supplier Name / Address** | | **Supplier Certified by** |
| e.g., Moulded components | e.g., MouldCo, Inc. California, USA | | e.g., NSAI |
|  |  | |  |
|  |  | | *Add lines as required* |
| List all potential commercial competitor(s) for **the medical device under review** | | | |
| **Client Product to be CE Marked with NSAI** | | **Potential Commercial Competitor Name(s)** | |
| e.g., Pregnancy Test | | CHG, Inc., Pregnancy Laboratories Inc., ACME Testing. | |
|  | |  | |
|  | | *Add lines as required* | |

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| **Signatures** | | | | |
| We, the manufacturer, 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. | | | | |
| Signed on Behalf of the Manufacturer | | | | |
| Please  Sign  /Date  Here |  |  | | |
| Print Name | |  | | |
| Position / Title: | |  | | |
| Contact Person details (if different): NA ☐ | | | | |
| Name:  Title: | | | | Email:  Phone: |
| **For NSAI Use Only** | | | | |
| Reviewer | | | Signed and Dated | |
| Technical | | |  | |
| Sterilisation | | |  | |
| Electrical | | |  | |
| Software | | |  | |
| Clinical Benefit Review | | |  | |
| External Expert | | |  | |
| Trainee | | |  | |
| By signing this, the reviewer confirms that they have no conflict of interest with the above-named company (e.g., training, consultancy, financial, personal, or political) that would affect the integrity of the technical review process and hence the review results and that this activity is not further subcontracted. | | | | |

## **Section 2**

**Technical Documentation**

**Instructions**

* All documentation must be in **English**.
* The complete Technical Documentation must be submitted in full. References to files from other products or previous submissions **are not accepted.**
* We do not accept hard copies of Technical Documentation.
* Documents must be provided in the form of **PDF files**, bookmarked, paginated, fully searchable.
* PDF files and attachments should not be file protected or locked.
* File names **must not be long**; they should be succinct and be accurate to the information contained within.
* Data must be of high quality; the duration of the review and the number of queries is dependent on the quality of the data received.

**How to Submit Technical Documentation**

* Manufacturers may submit one PDF file for **all required parts** as listed in Table 1 below

**or**

* Manufacturers may submit one PDF file for **each required part** as listed in Table 1 below.
  + Depending on the size and type of data, it may assist the review to split the data across more than one PDF file.
* All files submitted must be bookmarked, searchable and align to Section 3 – 12

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## Section 3: General Information

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| --- | --- | --- |
| The information in this section relates to the currently approved medical device. Do not include any information relating to the proposed change in this section. | | |
| G1 | NSAI File Number: | 746.XXX. |
| Proposed Significant Change Reference Number as per MTF-1028. |  |
| State the product(s) name associated with the proposed change |  |
| Device or Device Group Name: |  |
| Classification: |  |
| SRN: |  |
| EMDN |  |
| Please supply file number(s) for NSAI issued site QMS certificates for sites relevant to this submission. | |
| File Number: MD19.XXXX  Exp Date: **DD-MON-YYYY** | |
| Please state scope as currently approved under IVDR 2017/746: | |
| Scope: | |
| Provide details on any of the above if required: | |

## Section 4: Nature of Change

| **N - Nature of Change** | | |
| --- | --- | --- |
| N1 | Please confirm the proposed change as confirmed by CE Product Substantial Change Notification review.  Ensure the description of the proposed change is comprehensive, clear, non-ambiguous and considers the indirect impact on the approved device and associated technical documentation. | |
| Proposed change statement from MTF-1028: | |
| Are there additional changes to the above proposed change statement? If yes, provide details below.  Failure to disclose all changes at this point, will result in a delay and/or postponement of this review. | Yes ☐ No ☐ |
| Details: | |
| Confirm why this proposed change is being made: | |
| Details: | |
| N2 | Confirm an updated Declaration of Conformity compliant to Annex IV has been uploaded to the **N2 Folder**.  If no, provide details below. | Yes ☐ No ☐ |
| Confirm an updated GSPR checklist has been uploaded to the **N2 Folder**.  If no, provide details below. | Yes ☐ No ☐ |
| Details: | |

## Section 5: Intended Purpose of the Device

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| D – Device Description and Intended Purpose | | |
| D1 | State the **currently approved** intended purpose of the device. | |
| Currently Approved Intended Purpose: | |
| Does the proposed change impact the intended purpose **and/or** compliance relating to Annex II, Section 1? | No ☐ Yes ☐ |
| If no, provide a detailed justification: | |
| If yes, provide a detailed description of how the change has impacted the technical documentation relating to the intended purpose: | |
| Does the proposed change impact the device description **and/or** compliance relating to Annex II, Section 1 or any other applicable IVDR requirements? | No ☐ Yes ☐ |
| If no, provide a detailed justification: | |
| If yes, provide a detailed description of how the change has impacted the technical documentation relating to device description: | |
| Confirm that all supporting device description or intended purpose documents relating to the proposed change have been uploaded to the **D1 Folder.** | Yes ☐ No ☐ |
| **Note:** Supporting documents relating to the following should be submitted if they are impacted/relate to the proposed change; this list is non-exhaustive.   * Impact of change on components/accessories. * Changes to contraindications/warnings. * Principles of operation or key functional elements.   Ensure the changes/updates to existing approved documents can be clearly identified by the NSAI file reviewer, i.e., redline and final draft. Ensure documents are provided in searchable formats. | |

## Section 6: Labelling and IFU

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| **L – Labelling and IFU** | | |
| L1 | Does the proposed change impact labelling and/or the IFU / e-IFU **and/or** compliance relating to Annex I, Chapter III or any other applicable IVDR requirements? | No ☐ Yes ☐ |
| If no, provide a detailed justification: | |
| If yes, provide a detailed description of how the change has impacted the technical documentation relating to labelling and or the IFU / e-IFU: | |
| Confirm that all supporting labelling and/or IFU / e-IFU documents relating to the proposed change have been uploaded to the L1 Folder. | Yes ☐ No ☐ |
| **Note:** Supporting documents relating to the following should be submitted if they are impacted/relate to the proposed change; this list is non-exhaustive.   * Labels with changes clearly illustrated (i.e., redline and final draft). * IFU with changes clearly illustrated (i.e., redline and final draft). * Instruction manuals with changes clearly illustrated (i.e., redline and final draft). * Other as appropriate to articulate to change from the previously approved device. * Website updates relating to the change.   4wsxEnsure the changes/updates to existing approved documents can be clearly identified by the NSAI file reviewer, i.e., redline and final draft. Ensure documents are provided in searchable formats. | |

## Section 7: Risk Management

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| R – Risk Management | | |
| R1 | Does the proposed change impact risk management and/or compliance relating to Annex I, Chapter 1 or any other applicable IVDR requirements?  If no, provide details below. | Yes ☐ No ☐ |
| Details:  Supporting documents can be uploaded to the R1 Folder. | |
| Confirm compliance is claimed to EN ISO 14971:2019.  If no, provide details below. | Yes ☐ No ☐ |
| Details:  Supporting documents can be uploaded to the R1 Folder. | |
| Confirm risk documentation has been updated to reflect the proposed change.  **Note:** Ensure the proposed change has been addressed across risk analysis, evaluation, control, residual risk, and this assessment is contained in the risk management review, and production and post-production activities as appropriate. | Yes ☐ No ☐ |
| Provide a detailed description of how the change has impacted the technical documentation relating to risk management: | |
| Does the proposed change introduce new hazards or new hazardous situations? Provide details below. | Yes ☐ No ☐ |
| Details:  Supporting documents can be uploaded to the R1 Folder. | |
| Confirm the risk management assessment has been signed-off by those designated with responsibility for the review as per the risk management plan. Provide details below. | Yes ☐ No ☐ |
| Details:  Supporting documents can be uploaded to the R1 Folder. | |
| Confirm that all supporting risk management documents relating to the proposed change have been uploaded to the **R1 Folder**. | Yes ☐ No ☐ |
| **Note:** Supporting documents relating to the following should be submitted if they are impacted/relate to the proposed change; this list is non-exhaustive.   * Revised benefit-risk analysis * Revised FMEAs * Revised traceability matrix * Revised Risk management review/report   Ensure the changes/updates to existing approved documents can be clearly identified by the NSAI file reviewer, i.e., redline and final draft. Ensure documents are provided in searchable formats. | |

## Section 8: Sterilisation

|  |  |  |  |
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| S - Sterilisation | | | |
| S1 | Please submit the **Change Impact Assessment record** for review.  [**Note:** This change control document should present the assessment of the change, providing detail on the expected impact, the testing to be performed and the documentation to be generated/updated.] | | |
| S2 | Does the proposed change impact Sterilisation or any applicable IVDR requirements?  [Factors to consider include changes to the **Device Design**, **Device Packaging**, **Device Storage and Transportation, Sterilization Method, Sterilization Product Release Method (BI or Parametric Release),** etc.] | Yes ☐ No ☐ | |
| **If yes,** please detail ALL change(s) and define the sterilization testing performed to support the change(s). See table below for an example:   |  |  |  | | --- | --- | --- | |  | **Changes** | **Sterilisation testing performed** | | ***Change [Example]:*** | | | | *1* | *A change to the load configuration specifically a significant change in mass.* | *A full steam sterilization validation was completed in accordance with ISO 17665 standard.* | | *2* | *The secondary packaging (non-sterile barrier) is also changing.* | |  |  |  | |  |  |  | | | |
| **If no,** provide a justification for why the change(s) do not impact the sterile condition of the device(s) or the sterilization process: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| S3 | Please complete the below table with the information requested:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Sterilization Information Summary and Testing performed in support of change(s):** | | | | | | | **ALL Devices under scope**  **[Device Name & Identifier]** | **Device(s) tested (Representative)** | **Sterilisation Method**  **(Existing & Proposed)** | **Sterilization Provider**  **(Existing & Proposed)** | **Sterilisation Location**  **(Existing & Proposed)** | **Protocol #’s & Report #’s** | | ***Change [Example]:*** | | | | | | | *1.Pregnancy self-test Device A (A1234500)*  *2. Pregnancy self-test Device B (B1234500)*  *3. Pregnancy self-test Device C (C1234500)* | *\* Pregnancy self-test Device A (A1234500)* | ***Existing:***  *\_Moist Heat\_\_*  ***Proposed:***  *\_Moist Heat\_*  *(No change)* | ***Existing:***  *\_Sterilizer ABC\_\_\_*  ***Proposed:***  *\_Sterilizer ABC\_\_*  *(No change)* | ***Existing:***  *Sterilizer ABC,\_*  *57 Grafton St,\_ Dublin 4,\_ Ireland,\_ H91X123.\_\_*  ***Proposed:*** *Sterilizer ABC,\_ 12 Fontenoy St, Dublin 6, Ireland, H91X123\_\_ (Change to location of Steri provider)* | *1. Ster Validation Protocol (P123456)*  *2. Ster Validation Report (R123456)*  *3. Bioburden Test Reports (Attached to R123456)*  *4. EO Residual Test Reports (Attached to R123456)* | |  |  |  |  |  |  | |  |  |  |  |  |  |   *\*Where a representative device is used in the sterilization testing, ensure that a* ***rationale*** *is provided for how this device supports all of the devices in scope of the change(s). Please also provide a comparison between the tested device and the remaining devices under scope of the Significant Change below: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* | | |
|  | | |
| S4 | Is compliance with any of the following standards claimed?   |  |  |  | | --- | --- | --- | | EN ISO 11135-1 (Ethylene Oxide (ETO)) | Yes ☐ | No ☐ | | EN ISO 11137-1 (Irradiation) | Yes ☐ | No ☐ | | EN ISO 11137-2 (Irradiation) | Yes ☐ | No ☐ | | EN ISO 13408 (Aseptic Processing) | Yes ☐ | No ☐ | | EN ISO 17665-1 (Moist Heat) | Yes ☐ | No ☐ | | ISO 22441 (Vaporized Hydrogen Peroxide) | Yes ☐ | No ☐ |   If no, please include a **justification** and demonstrate how the requirements of the IVDR 2017/746 are met: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| S5 | Confirm that all supporting Sterilisation documents relating to the proposed change have been uploaded to the **S1 Folder**. | | Yes ☐ No ☐ |
|  | **Note:** Supporting documents relating to the following should be submitted if they are impacted/relate to the proposed change; this list is non-exhaustive.   * Validation data. * If device is sterilised via EO, documents relating to bioburden data, duration of contact (limited/prolonged/permanent exposure), etc. * If device is sterilised via Irradiation, documents relating to irradiation process, dose setting method etc. * If device is sterilised via moist heat, documents relating to type of cycle (pre-vac, gravity or other) etc. * Data on maintenance of the sterile barrier system. * Shelf life/stability data.   Ensure the changes/updates to existing approved documents can be clearly identified by the NSAI file reviewer, i.e., redline and final draft. Ensure documents are provided in searchable formats. | | |
|  | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Packaging and Sterile Barrier System (SBS) | | | | |
| SBS1 | Please submit the Change Impact Assessment record for review.  [**Note:** This change control document should present the assessment of the change, providing detail on the expected impact, the testing to be performed and the documentation to be generated/updated.] | | | |
|  | Does the proposed change impact the packaging of the device(s)?:  **[Note:** Consider if the change impacts the devices packaging that has function in maintaining the sterile barrier system (SBS) and/or the packaging integrity. Examples of changes include but are not limited to changes to the packaging design, characteristics, dimensions, materials, specifications, contents, configuration, density, porosity, change(s) impacting storage/transportation conditions, bioburden, sterilant residual levels, shelf-life etc.] | Yes ☐ No ☐ | | |
| If **yes,** please detail ALL changes planned and define the current and proposed packaging design for each device/device family under scope:  **Changes Planned:**  1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  2.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  3.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  4.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Current packaging design:**  ***[Note: Pictures/illustrations/Schematics may be included to aid in understanding]***  **Proposed packaging design:**  ***[Note: Pictures/illustrations/Schematics may be included to aid in understanding]*** | | | |
| If **no**, provide a **rationale** for why the packaging is not affected’  ~~-----------------------------\_~~ | | | |
| SBS2 | Does the proposed change affect the **sterility** or **microbial state** of the device?  [Consider for example: if the change to packaging could reduce the transfer of heat, humidity or impact sterilant gas penetration, or is the change to packaging material which could elevate product bioburden and thus affect the existing supporting sterilization validation]. | | | Yes ☐ No ☐ |
| **If yes,** please elaborate on how the sterility or microbial state of the device may be impacted and record the testing performed in Table 1 below:  ~~-----------------------------\_~~ | | | |
| **If no**, provide a **rationale** below:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
| SBS3 | Does the proposed change affect the **stability** of the packaging used for the device(s)?  If no, please provide a rationale below: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | Yes ☐ No ☐ |
| SBS4 | Does the change to packaging, affect the existing **storage or transportation conditions** for the device(s) and thus require further transportation studies (e.g. environmental conditioning, distribution simulation testing) to be performed?  **If yes**, record the testing performed in Table 1 below.  **If no,** provide a **rationale** below:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | Yes ☐ No ☐ |
|  | Please outline the **new** testing performed to support the change(s) by completing **Table 1** with the information requested.  **Note:** If it is determined that certain testing is not required to be repeated in support of the proposed change(s) to be implemented, please record any existing/previously approved testing that is also being used to support the amended device(s) in Table 1 and identify as \*\***LEVERAGED** (See example). The inclusion of a justification for leveraging existing data is also required in section below Table 1.   |  |  |  |  | | --- | --- | --- | --- | | **TABLE 1: Packaging Information Summary and Testing performed in support of change(s):** | | | | | **ALL Devices under scope**  **[Device Name & Identifier]** | **Device(s) tested (Representative)** | **Testing performed:**  **(New and Leveraged)** | **Packaging Protocol #’s & Report #’s** | | ***Change [Example]:*** | | | | | *1.Pregnancy Self-test Device A (A1234500)*  *2. Pregnancy Self-test Device B (B1234500)*  *3. Pregnancy Self-test Device C (C1234500)* | ***\**** *Pregnancy Self-test Device A (A1234500)* | *Packaging DV Testing (Time 0 & to Shelf-life)*  *Transport Simulation Testing* | *1. Packaging Design Verification Test Protocol (P123456)*  *2. Packaging Design Verification Test Report (R123456)*  *3. Transport Simulation Test Protocol (P023456)*  *4. Transport Simulation Test Report (R023456)*  *5. Packaging Design Verification Test Protocol (P123456) [Accelerated Aging] -\*\*****LEVERAGED.***  *6. Packaging Design Verification Test Report (R123456) [Accelerated Aging] -\*\*****LEVERAGED.*** | |  |  |  |  | |  |  |  |  |   ***\*****Where a* ***representative device*** *is used in the packaging testing, ensure that a* ***rationale*** *is provided for how this device supports all of the devices, in scope of the change(s). Please also provide a comparison between the tested device and the remaining devices under scope of the Significant Change below: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*  \*\**Ensure that a* ***rationale*** *for* ***leveraging*** *existing test data on pre-amended device(s) has been provided below: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* | | | |
| SBS5 | Confirm that all supporting packaging documents relating to the proposed changed device(s) have been uploaded to the **SBS Folder**. | | Yes ☐ No ☐ | |
|  | **Note:** Supporting documents relating to the following should be submitted if they are impacted/relate to the proposed change; this list is non-exhaustive.   * Data on maintenance of the sterile barrier system. (Packaging Verification Test Protocol, Packaging Verification Test Report, Transport Test Protocol and Report) * Shelf life/stability data. | | | |

## Section 9: Medical Electrical Equipment, Systems and Software

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| ME Equipment and ME Systems | | |
| E1 | Does the proposed change impact medical electrical equipment, systems and software or any applicable IVDR requirements? | No ☐ Yes ☐ |
| If no, provide a detailed justification: | |
| If yes, provide a detailed description of how the change has impacted the technical documentation relating to medical electrical equipment, systems and software: | |
| Please provide all documentation to demonstrate compliance to necessary standards: | |
| Confirm that all supporting medical electrical equipment, systems and software documents relating to the proposed change have been uploaded to the **E1 Folder.** | No ☐ Yes ☐ |
| **Note:** Supporting documents relating to the following should be submitted if they are impacted/relate to the proposed change; this list is non-exhaustive.   * . Change impactingapplicable requirements of EN 60601-1 latest version. * Change impacting applicable requirements of EN 60601-1-2 latest version, including corresponding EMC Declaration included in Instructions for use. * Expected Service Life of the device. * Change relating to incorporated Software/Firmware. * Change impacting conformance to MDCG-2019-16 Guidance on Cybersecurity for Medical Devices. * Change impacting compliance with EN 62304. * Change impacting safety classification (A, B, C) as per EN 62304 and rationale for each software or firmware unit.   Ensure the changes/updates to existing approved documents can be clearly identified by the NSAI file reviewer, i.e., redline and final draft. Ensure documents are provided in searchable formats.. | |

## Section 10: Design Verification and Validation

|  |  |  |
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| **V – Verification of Design** | | |
| V1 | Does the proposed change impact design or design verification **and/or** compliance relating to Annex II, Section 6 or any other applicable IVDR requirements? | No ☐ Yes ☐ |
| If no, provide a detailed justification: | |
| If yes, provide a detailed description of how the change has impacted the technical documentation relating to verification of design: | |
| Has the change impacted the stability or shelf life of the device?  Provide details below. | Yes ☐ No ☐ |
| Details: | |
| Confirm that all supporting verification of design documents relating to the proposed change have been uploaded to the **V1 Folder.** | Yes ☐ No ☐ |
| **Note:** Supporting documents relating to the following should be submitted if they are impacted/relate to the proposed change; this list is non-exhaustive.   * Updated manufacturing governing document (manufacturing procedure). * IQ/OQ/PQ plans and reports. * Updated copy of the finished product release specifications and final product testing.   Ensure the changes/updates to existing approved documents can be clearly identified by the NSAI file reviewer, i.e., redline and final draft. Ensure documents are provided in searchable formats. | |

## Section 11:Performance Evaluation

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| **PE – Performance evaluation** | | |
| PE1 | **Note:** As per MDCG 2021-5 it is commonly considered that the most recent versions of standards, with the technical solutions they contain, reflect the “state of the art”. However, compliance with the most recent version of any standard not listed in the OJEU does not automatically imply compliance with the requirements of the IVDR 2017/746. | |
| Does the proposed change performance of the device | Yes ☐ No ☐ |
| If no, provide a detailed justification: | |
| If yes, please provide the necessary performance evaluation report to support the safe use of the device following the change. These data should arise from studies in a clinical or other appropriate environment or result from relevant biological references. | |
| Does the proposed change affect the following:  ☐ Analytical performance  ☐ Accuracy  ☐ Analytical Sensitivity and/or specificity  ☐ Linearity  ☐ Clinical performance  ☐ Measuring function  ☐ Measuring range  ☐ Specimen type  ☐ Others: Please state for e.g. carryover/ Handling requirements | |
| Please state what standards/ guidances are using for testing performance evaluation studies. If no standards/guidance was used, please provide justification: | |
|  | |
| Confirm that all supporting performance evaluation documents related to proposed change have been uploaded to the **PE Folder.** | Yes ☐ No ☐ |
|  | **Note:** Supporting documents relating to the following should be submitted if they are impacted/relate to the proposed change; this list is non-exhaustive.   * Change to the limits of accuracy. * Change in units of measurement. * Change in measurement, monitoring and display scale.   Ensure the changes/updates to existing approved documents can be clearly identified by the NSAI file reviewer, i.e., redline and final draft. Ensure documents are provided in searchable formats. | |

## Section 12: Harmonised Standards and Common Specifications

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| **HS – Harmonised Standards and Common Specifications** | | |
| HS1 | **Note:** As per MDCG 2021-5 it is commonly considered that the most recent versions of standards, with the technical solutions they contain, reflect the “state of the art”. However, compliance with the most recent version of any standard not listed in the OJEU does not automatically imply compliance with the requirements of the MDR 2017/745. | |
| Does the proposed change impact use of harmonised standards, common specifications or other standards to which compliance has been claimed? | Yes ☐ No ☐ |
| If no, provide a detailed justification: | |
| If yes, provide a detailed description of how the change has impacted the technical documentation relating to harmonised standards, common specifications:  **Location:**  **File Name:**  **Page:**  **Note:** | |
| Confirm that all supporting standards/specificationdocuments relating to the proposed change have been uploaded to the **HS1 Folder.** | Yes ☐ No ☐ |

## Section 13: Performance/Complaint Analysis

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| **PC – Performance/Complaint Analysis** | | |
| PC1 | Has the change been made as a result of performance, feedback or complaints? | No ☐ Yes ☐ |
| If no, provide a detailed justification: | |
| If yes, provide a detailed description of how the change has impacted the technical documentation relating to performance/complaints: | |
| Confirm that all supporting performance/complaints **documents and data** relating to the proposed change have been uploaded to the **PC1 Folder.** | Yes ☐ No ☐ |
| **Note:** Supporting documents relating to the following should be submitted if they are impacted/relate to the proposed change; this list is non-exhaustive.   * Trend analysis (only related to performance and complaints with respect to the proposed change). * Individual Complaints (only related to performance and complaints with respect to the proposed change). * Reportable incidents (only related to performance and complaints with respect to the proposed change). * CAPA (only related to performance and complaints with respect to the proposed change).   Ensure the changes/updates to existing approved documents can be clearly identified by the NSAI file reviewer, i.e., redline and final draft. Ensure documents are provided in searchable formats. | |