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| **INSTRUCTIONS** |
| **Important: Please read and follow these instructions carefully:**   * All documentation must be in **English**. * **Before you begin, please ensure the accompanying ‘Data Folder Set’ for this Class has been downloaded.** * Data and supporting documents must be uploaded using this New Product Data Folder set, where each question has a corresponding Folder. * File names **must not be long**; they should be accurate and succinct. * When the same document is used to support more than one question it **must** be uploaded to each relevant Folder. * Supporting documents must be provided in a **readily searchable** format. * Please complete **all sections** of the form, where a section is not relevant a justification must be provided by the manufacturer. * When referencing supporting documentation **clearly indicate page numbers** that address all relevant parts of the specific question, if applicable. * 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.   **The review will not begin until data is received in this format. Repeat failure will result in cancellation of review.**  All forms and supporting data can only be submitted via the NSAI upload facility: <https://www.nsaiinc.com/upload/cemarking/>  For any queries on how to complete this form please contact: [medical.devices@nsai.ie](mailto:medical.devices@nsai.ie) |

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| **Signatures** | | | | | |
| We declare the information in this form is correct and has been submitted as per the instructions listed above. Failure to do so may result in prolonged review time, delays, or termination of review. | | | | | |
| **Sign and Date on Behalf of the Manufacturer** | | | | | |
| Sign/ Date  Here | ▶ |  | | | |
| Print Name | |  | | | |
| Position / Title: | |  | | | |
| Email: | |  | | Phone Number: |  |
| **For NSAI Use Only** | | | | | |
| **Reviewer** | | | **Signed and dated** | | |
| Technical | | |  | | |
| Sterilisation | | |  | | |
| Biocompatibility | | |  | | |
| Clinical | | |  | | |
| Mech. Functional Safety | | |  | | |
| Electrical | | |  | | |
| Software | | |  | | |
| 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. | | | | | |

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| **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., Sterilisation | e.g., SterCo, 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., Transcatheter aortic valve replacement | | ValveTech, Inc., ABC Valves, ACME Valves, | |
|  | |  | |
|  | | *Add lines as required* | |
| **For NSAI Impartiality Officer Review Only** | | | |

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| **Before you begin, ensure the associated ‘Data Folder Set’ is ready.** |

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| G - Currently Approved General Information | | | | | | |
| 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: | | | 745.XXX. | | |
| Proposed Significant Change Reference Number as per MTF-1028. | | |  | | |
| PO Number, if required: | | |  | | |
| Manufacturer:  **(as per meaning within the regulation)** | | |  | | |
| Address: | | |  | | |
| EU Authorised Representative: | NA | | Name:  Address:  Email:  Telephone: | | |
| Name of Person Responsible for Regulatory Compliance: | | |  | | |
| Company Liaison and Details: | | | Name:  Address:  Email:  Telephone: | | |
| State the product(s) name associated with the proposed change | | | | |  |
| Generic Device Group: | | NA | | Group: | |
| GMDN/EMDN | |  | | | |
| Manufacturers SRN (single registration number): | | | | |  |
| Please supply file number(s) for NSAI issued site QMS certificates for sites relevant to this submission. | | | | | |
| File Number: **MD**.19.XXXX  Exp Date: **DD-MON-YYYY** | | | | | |
| Please state scope as currently approved under MDR 2017/745: | | | | | |
| Scope: | | | | | |
| Provide details on any of the above if required: | | | | | |

| 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 |
| Confirm if the proposed change has impacted the shelf life/stability.  If yes provide details below and ensure supporting documents have been uploaded to the **N2 Folder**. | Yes  No |
| Details: | |

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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 MDR 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. | |

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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 MDR 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. | |

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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 MDR 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.   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. | |

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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? | 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 harmonised standards, common specifications: | |
| Confirm that all supporting standards/specificationdocuments relating to the proposed change have been uploaded to the **HS1 Folder.** | Yes  No |

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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. | |

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| **S - Sterilisation** | | |
| S1 | Does the proposed change impact Sterilisation or any applicable MDR 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 Sterilisation: | |
| 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. | |

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| **MF – Measuring Function** | | |
| MF1 | Does the proposed change impact the measuring function of the device or any applicable MDR 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 measuring function: | |
| Confirm that all supporting measuring function documents relating to the proposed change have been uploaded to the **MF1 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. | |

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| **RD – Reprocessed Device** | | |
| RD1 | Does the proposed change impact aspects that relate to the reprocessing of the device **and/or** compliance relating to Article 17 **or any** other applicable MDR 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 the reprocessed device: | |
| Confirm that all supporting reprocessed documents relating to the proposed change have been uploaded to the **RD1 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.   * Procedures relating to cleaning and disinfection. * Validation governing document (procedure or equivalent).   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. | |

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| PS – Procedure Pack/System | | |
| PS1 | Does the proposed change impact aspects relating to procedure pack/system or any applicable MDR 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 procedure pack/system: | |
| Confirm that all supporting procedure pack/system documents relating to the proposed change have been uploaded to the **PS1 Folder**. | Yes  No |

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| RS – Reusable Surgical Instrument | | |
| RS1 | Does the proposed change impact aspects relating to the reusable surgical instrument or any applicable MDR 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 the reusable surgical instrument: | |
| Confirm that all supporting reusable surgical instrument documents relating to the proposed change have been uploaded to the **RS1 Folder**. | Yes  No |