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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 | | |
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| 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: | |

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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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| V – Verification of Design | | |
| V1 | Does the proposed change impact design or design verification **and/or** compliance relating to Annex II, Section 3 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 verification of design: | |
| Has the change impacted the stability or shelf life of the device?  Provide details below. | No  Yes |
| 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. | |

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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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| **BC - Biocompatibility** | | |
| BC1 | Does the proposed change impact Biocompatibility 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 Biocompatibility: | |
| Confirm that all supporting Biocompatibility documents relating to the proposed change have been uploaded to the **BC1 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 Biological Evaluation Plan and Report. * Updated tests protocols. * Tests considered (cytotoxicity, sensitisation, implantation, etc.).   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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| **E – Medical Electrical (ME) Equipment, Systems & Software** | | |
| E1 | Does the proposed change impact medical electrical equipment, systems and software 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 medical electrical equipment, systems and software: | |
| Confirm that all supporting medical electrical equipment, systems and software documents relating to the proposed change have been uploaded to the **E1 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 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. | |

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| **FS – Mechanical Functional Safety** | | |
| FS1 | Does the proposed change impact the mechanical functional safety of the device? | No  Yes |
| If no, provide a detailed justification: | |
| If yes, provide a detailed description of how the change has impacted the technical documentation relating mechanical functional safety: | |
| Confirm that all supporting mechanical functional safety documents relating to the proposed change have been uploaded to the **FS1 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.   * Changes to design of approved device. * Updated design drawings/functional drawings/exploded drawings and all relevant 2D/3D/exploded/animated drawings/illustrations include details to illustrate all components, their composition, and technical dimensions. * Design Traceability Matrix or Design Input/ Output document. * Design Verification Testing (protocols and reports), substantiating that the Design Outputs meet the Design Inputs. * Characteristics and performance of the device at the proposed product lifetime have been evaluated/tested. * Animal model studies, computer model studies. * Device stability and shelf life. * documented overview, of manufacturing process(es) (i.e., process flow) including any activities performed by, or products/components obtained from, suppliers relating 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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| **C – Clinical Performance** | | |
| C1 | Does the proposed change impact the clinical performance of the device or any other applicable MDR requirements? | No  Yes |
| If no, provide a detailed justification: | |
| If yes, provide a detailed description of how the clinical performance is affected by the change: | |
| Has additional clinical data been provided to support the safety and performance of the device following the proposed change(s)? | Yes  No |
| Specify what type of clinical data has been provided and state the chosen route for clinical evaluation (equivalence, clinical investigation, etc).  **Note 1:** Clinical Investigations must comply with the MDR requirements regarding clinical investigations.  **Note 2:** Equivalence claim must comply with the MDR requirements regarding equivalence. | |
| Article 61(3)  Article 61(4)  Article 61(5)  Article 61(6a)  Article 61(6b)  Article 61(9)  MDCG 2020-6 Section 1.2  (See clinical Pathway white paper on NSAI website) | |
| Type of clinical data: | |
| Has the CER been updated to include a detailed discussion of the change(s) and rationale for them?  **Note:** Where clinically relevant changes are made, the CER must be updated. | Yes  No |
| Confirm that all relevant documents below have been updated based on the proposed changes made and have been uploaded to the **C1 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.   * Changes in the intended purpose, indications for use, contraindications or warnings, uploaded to the C1 Folder. * CVs and declarations of interest of listed evaluators including that of the Clinical expert(s), uploaded to the C2 Folder. * Revised CEP & CDP, uploaded to the C3 Folder. * Revised CER, uploaded to the C4 Folder. * Revised CIP and CIR, uploaded to the C5 Folder. * Revised literature search protocol and report, uploaded to the C6 Folder. * Changes in the device population, uploaded to the C6 Folder. * Revised IFU and labelling documentation, uploaded to the C7 Folder. * Revised Implant card, uploaded to the C7 Folder. * Revised Risk documentation, uploaded to the C8 Folder. * Revised PMS plan and PMCF plan if impacted by the proposed change, uploaded to the C9 Folder. * Revised SSCP, uploaded to the C10 Folder.   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. Ensue redline copies are submitted to depict changes made. | |

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| EQ - Equivalence | | |
| EQ1 | Does the proposed change impact claimed Equivalence as per MDR Annex XIV, Part A, Section 3 & MDCG 2020-5? | 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 claimed equivalence: | |
| Confirm that all supporting equivalence documents relating to the proposed change have been uploaded to the **EQ1 Folder.** | Yes  No |

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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 |

### **Appendix A**

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| **MS – Medicinal Substances** | | |
| MS1 | Does the proposed change impact the medicinal substance? | 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 medicinal substance: | |
| Does the proposed change impact the manufacturing method/manufacturing location/release location etc. of the Medicinal substance? | 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 medicinal substance: | |
| Confirm that all supporting medicinal substance documents relating to the proposed change have been uploaded to the **MS1 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.   * Any change to the approved EMA or CA opinion. * Changes altering the statement of usefulness for the medicinal substance. * Description of the substance and constituents including the amount (giving a range where appropriate) of the medicinal substance incorporated into each medical device. * Changes to the specification of the medical device. * Qualitative and quantitative tests carried out to control the medicinal substance in the device. * the results of the toxicity tests should be supplied for any new active substances. * Changes to the stability data pertaining to the use of Medicinal Substances. * Changes to release process/location.   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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| TAO – Tissues of Animal Origin | | |
| TAO1 | Does the proposed change impact aspects that relate to tissues of animal origin? | 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 tissues of animal origin: | |
| Confirm that all supporting tissues of animal origin documents relating to the proposed change have been uploaded to the **TAO1 Folder**. | Yes  No |
| **Note:** The following supporting documents may need to be submitted; this list is non-exhaustive.   * Change impacting compliance with Regulation (EC) 1609/2000 (where the raw material or intermediates are imported or processed in the EU): * Change that impacts the valid EDQM certificate. * Change to method of animal tissue harvesting. * Change on all inactivation steps, including those related to TSE infectious agents if applicable. * Change on all clearance validation steps, including those related to TSE infectious agents if applicable. * Change on the source of tissue, ensuring to include geographical location, open/closed herds, feeds, pre- and post-mortem inspection. * Change to the production process. * Changes to release process/location.   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. | |