

**Medical Devices**

# Application Form

* **Class 2B Implantable**
* **Class 3**
* **AIMD**

**Please tick all that apply:**

|  |  |  |  |
| --- | --- | --- | --- |
| [ ]  | Class 2B Implantable |  |  |
| [ ]  | Class 3 |  |  |
| [ ]  | AIMD |  |  |
| [ ]  | TSE |  |  |
| [ ]  | Human Blood |  |  |
| [ ]  | Medicinal Substance |  |  |
|  |  |  |  |
| [ ]  | Transfer (from another NB) |  |  |
| [ ]  | Modular (partial application) |  |  |
|  |  |  |  |
| [ ]  | Fast Track (expedited) |  |  |
|  |
| PO Number |       |
|  |
| **Directive(s) that apply:** | **NSAI File Number** |
| [ ]  | MDD (93/42/EEC)  | 252.     /      |
| [ ]  | AIMD (90/385/EEC) | 253.     /      |
| [ ]  | TSE | [ ]  | Human Blood | [ ]  | Medicinal Substances |

|  |  |
| --- | --- |
| Legal Manufacturer’s Name |  |
| Legal Manufacturer’s Address |  |

|  |
| --- |
| INSTRUCTIONS |
| 1. Please complete all relevant sections of the form (excluding the NSAI Review sections).
2. Please enter as much information onto the form as possible - avoid entering “see Technical File/Design Dossier”. If the data is in the supporting documentation, please ensure that there is a clear reference to the exact location of this information.
3. Please submit an unsigned version of this Application in Word as well as a signed copy - either scanned/secured (pdf) copy.
4. All application forms and supporting data to be forwarded in soft copy via one of the following (Hard copies not required)

NSAI upload facility : see <http://www.nsaiinc.com/>1. Supporting documents should be provided in a SEARCHABLE format
2. Applications and supporting documentation must be in English
3. Please send a representative sample of the device(s). This is particularly important for new/novel devices. Any video or animations of procedures/simulated use would also be helpful, if available.
 |

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|  |
| --- |
| APPLICANTS’ SUBMISSION CHECKLIST |
|  | Completed application form (Word format, .doc or .docx)  |
|  | Application (min. Signed Declaration page(s)) scanned |
|  | QMS certificates for all sites in Table 1  |
|  | Draft Declaration of Conformity |
|  | Labelling & IFU – May be Drafts |
|  | Essential Requirements Checklist including Harmonised Standards |
|  | Performance/Complaint Analysis |
|  | Risk Management documentation |
|  | Sterilisation Validation(s) – if sterile/intended to be sterilised |
|  | Biocompatibility data – if necessary |
|  | Electrical Safety Testing data – if necessary |
|  | Software/firmware lifecycle documents – if necessary |
|  | Bench Testing data – if necessary |
|  | Clinical Evaluation Report(s) per MEDDEV 2.7.1 |
|  | Clinical Evaluation procedure |
|  | Clinical investigation(s) report(s) and supporting documents per MEDDEV 2.7.1 |
|  | if following literature review/ equivalent device route please complete and attach NSAI Equivalence form GRF-25-28 if following literature |
| **For Transfers** |
|  | Copy of existing Notified Body Certificate(s) |
|  | Transition Plan |
|  | Contact details for existing Notified Body, including formal permission to contact existing Notified Body. |
| ***(NSAI will not contact the existing Notified Body*** ***prior to agreement with the Manufacturer)*** |
| **For Tissue of Animal Origin falling under TSE Regulation 722/2012 EU**  |
|  | Please complete Appendix A |
| **For Human Blood Derivatives** |
|  | Please complete Appendix B |
| **For Medicinal Substances** |
|  | Please complete Appendix C |

|  |
| --- |
| DECLARATION(S) BY APPLICANT |
| In making this application we declare:* The information in this form is correct
* We have not lodged an application with any other notified body to undertake conformance assessment procedures for the same product(s) / device-related quality system mentioned.
* We undertake to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective actions and notifications, taking account of the nature and risks in relation to this product.
* We agree to provide all vigilance reports to the Competent Authorities and NSAI
* We agree to pay all applicable fees and understand that non-payment of fees will result in withdrawal of approval.
* We undertake to fulfil the obligations imposed by the quality system approved
* We undertake to keep the approved quality system adequate and efficacious.
* We agree to inform NSAI that approved the quality system of any plan for substantial changes to the quality system or the product-range covered.
* We shall submit to NSAI any changes to the approved design, wherever the changes impact conformity with the essential requirements of the Directive or with the conditions prescribed for the use of the device.
* We authorise NSAI to carry out all the necessary inspections at the legal manufacturer, critical sub-contractors and / or crucial supplier facilities and will supply NSAI with all relevant information to accomplish the above and in particular the following:
* The documentation on the quality system
* The data stipulated in the part of the quality system relating to design, such as the results of analyses, calculations, tests etc., (where relevant)
* The data stipulated in the part of the quality system relating to manufacture such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.
* We authorize and agree to allow NSAI access to all critical subcontractors and crucial suppliers, and all sites where the device or it’s crucial components are produced.
* We agree to allow NSAI access to the Legal Manufacturer’s premises, and /or any of the above listed sites at any time for the purposes of performing unannounced audits.
* As necessary we agree to provide all necessary support in acquiring the necessary travel papers, including VISA, to facilitate NSAI access to the above listed locations.
* We agree to inform NSAI of the periods when the devices identified in this application will not be manufactured.
* We understand that NSAI may end this contract with the Legal Manufacturer if permanent unannounced access to the above listed sites is no longer assured.
* We understand that NSAI may cancel any unannounced audit at any time if the safety and security of NSAI personnel cannot be assured.
 |
| **By signing below, I accept the above declarations** |
| Signedon behalf of the Manufacturer: |  | Date: |  |
| Name (please print): |  |
| Position / Title: |  |
| Contact person(if different to Manufacturer): |  |
| e-mail: |  | Phone: |  |

|  |
| --- |
| Section 1: Manufacturer and Product Details |
| Note the “Manufacturer” as defined by the Directive(s) is “the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party. |

| **Table 1 – Manufacturers Information & Summary Product Data** |
| --- |
| Legal Manufacturer’s Name  |  |
| Legal Manufacturer’s Address |  |
| Design Site(s): |  |
| Manufacturing Site(s):(i.e. sites of actual manufacture) |  |
| Assembly Site(s) if applic.: |  |
| Sterilisation Site(s) if applic.: |  |
| Scope of Site(s):(i.e. as shown on the QMS cert) |  |
| Name and address of EU Authorised Representative(if applicable) |  |
|  |  |
| Product/Product Family Name:(In compliance with NB/MED/2.5.1/REC4 & NBOG’S Best Practice Guide 2006-2) |  |
| GMDN Reference Number: |  | See [www.gmdnagency.com](http://www.gmdnagency.com) |
| [ ]  | Declaration of Conformity included - Location within submission :  |  |
| **AIMD ONLY:** |
| Conformity Assessment | Annex | [ ]  | II |

|  |  |
| --- | --- |
| [ ]  | III (+V) |

 |
| Full QA | Type testing +Prodn QA |
| **MDD ONLY:** |
| Class | [ ]  | III | [ ]  | IIb(implantable) | Rule(s) |  |
| Rationale |  |
| Conformity Assessment | Annex | [ ]  | II | [ ]  | III (+V) |
| Full QA | Type testing +Prodn QA |  |
| **ALL DEVICES:** |
| Clinical Strategy-- Clinical data from: | [ ]  | Clinical Investigation  |
| [ ]  | Literature (Equivalence)  |
| [ ]  | Combination |
| Date of this application(i.e. date of Declaration of Applicant): |  |

| Please complete the Table below, providing a full and up-to-date list of the current model numbers and descriptions related to this Application.If the Declaration of Conformity is being used (instead of completing Table 2), please make sure that the WORD version is supplied. |
| --- |
| Table 2 – Product Family Information |
| **Sub-Family** | **Model/Catalogue Number** | **Description** | **Class** |
|  |  |  |  |
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| SECTION 2: DESCRIPTION OF DEVICE |
| --- |
| Please provide a full description of the device which demonstrates that the product is covered under the relevant Directive: |
| Device Description: |

| SECTION 3: INTENDED USE OF THE DEVICE |
| --- |
| 1. | Please enter a full description of the intended use of the device, which supports the product classification: |
|       |
| 2. | List of any contra-indications :  |
|       |
| 3. | List of any precautions / warnings : |
|       |

| Section 4: Previous Existing Legislation |
| --- |
| 1. | Does the device have any existing approvals (e.g. FDA 510(k)) | [ ]  | Yes | [ ]  | No |
| 2. | If “Yes” – please advise |       |
| 3. | Does this product, labelled with your Name & Address carry CE Marking with another Notified Body  | [ ]  | Yes | [ ]  | No |
| If “Yes” – this is considered a TRANSFERPlease refer to applications checklist on page #5 |

| Section 5: Labelling and IFU |
| --- |
| 1. | 1. Location of the sample Label(s) & IFU
2. in the supporting documentation
 |       |
| **Please include all levels of labelling – device, packaging, carton, etc.**Note - Draft labelling is acceptable for New Applications |
| 2. | Are copies of all labelling provided? | [ ]  | Yes | [ ]  | No |
| If No please rationalize that the sample provided is representative of the family |
|       |
| 3. | Is the IFU being provided electronically? | [ ]  | Yes | [ ]  | No |
| If “Yes”, please submit evidence of compliance with Council Regulation 207-2012 for electronic IFU. |
| 4. | Please advise how language requirements of the countries where the device is to be placed on the market have been fulfilled - |
|       |
| 5. | Are symbols being utilized in product labeling or IFU’s . | [ ]  | Yes | [ ]  | No |
| If yes are symbols in compliance with– |
| EN 1041: |       | EN ISO 980: |       |
| 6. | If compliance with these vertical labelling standards is not claimed, please justify - |
|       |

| Section 6: Solutions to Essential Requirements and Harmonised Standards |
| --- |
| 1. | Location of the revised solutions to Essential Requirements in the supporting documentation  |
|       |
| The recommended format for the Essential Requirements Checklist is shown in the GHTF Document GHTF/SG1/N011:2008 (STED).Manufacturers should include **Reference to supporting controlled documents -** this column should contain the reference to the actual technical documentation that demonstrates conformity to the essential requirement(s), i.e. the certificates, test reports, validation reports, study reports or other documents that resulted from the method used to demonstrate conformity and its location within the Technical File/Design Dossier. |
| 2. | Are Harmonised Standards being used | [ ]  | Yes | [ ]  | No |
| If “No” please justify - |
|       |
| 3. | Please list the relevant Harmonised Standards in Table 2 below |
|

| **TABLE 3 – Applicable Harmonised Standards List** |
| --- |
| **Standard** | **Year** | **Has the Standard been applied in full****Yes / No** |
|  |  |  |
|  |  |  |
|  |  |  |
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| Section 7: PERFORMANCE/COMPLAINT ANALYSIS |
| --- |
| 1. | Is there a product history for this device | [ ]  | Yes | [ ]  | No |
| If “No” please identify equivalent device(s) and relevant performance data |
|       |
| a. | What is the time period of the data being provided – |       |
| b. | **What are the:** |
| Total no. units placed on the market worldwide) |       |
| Total no. of complaints worldwide |       |
| Total Number of EU Vigilance Reports |       |
| 2. | Please provide: |
| * Trended analysis (graphical form) of the data over the stated period of time.
 |
| * Summary table of the individual complaints, with quantity and % total sales
 |
| 3. | Please summarize all global Vigilance issues that fulfill the European Reporting requirements in the following/similar format: |
|

| **TABLE 4:** |
| --- |
| **Report No.** | **Competent Authority** | **Details of investigation** | **Root Cause** | **CAPA Raised****Y/N****Details** | **Status** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
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|  |  |  |  |  |  |

**Note: Please supply this table as an attachment to the submission** |

| Section 8: Risk Management |
| --- |
| **1.** | 1. Is Compliance being claimed to EN ISO 14971:2012
 | [ ]  | Yes | [ ]  | No |
| **2.** | 1. Please provide the document number of the Risk Analysis Matrix / Risk assessment summary matrix/documents and location within the technical file supplied -
 |
|       |
| **3.** | 1. Please provide a traceability matrix linking the contraindications, warnings and precautions from Risk Management File to the Instructions For Use and CER
 |
| Please indicate where in the risk management file the overall residual risk conclusion is located |

| Section 9: Sterilisation |
| --- |
| 9.1 Sterilisation Validation |
|  **For devices provided sterile** |
| **1.** | Please provide the necessary sterilisation validation protocol(s) & report(s) and populate Table 5 below |
| [ ]  | Initial validation information: Year       |
| [ ]  | Latest revalidation (if initial validation >1yr) |
|

| **Table 5 – Sterilisation Information Summary**  |
| --- |
| **Device****sub-family** | **Cat.****Number** | **Sterilisation Method** | **Sterilisation Location** | **Protocol / Report No.** | **Site Resp for Release** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
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 |
|  | 1. | Is EtO used for Sterilisation of the device(s)If “No” please go to Question #2 below. | [ ]  | Yes | [ ]  | No |
| Is compliance with EN ISO 10993-7 latest version claimed  | [ ]  | Yes | [ ]  | No |
| If “No” please explain |  |
| Is compliance with EN ISO 11135 latest version claimed  | [ ]  | Yes | [ ]  | No |
| If “No” please explain |  |
| Please categorise the device according to the duration of contact |
| [ ]  | A – Limited Exposure |
| [ ]  | B – Prolonged Exposure |
| [ ]  | C – Permanent Contact |
|  | 2. | Is irradiation used for Sterilisation of the device(s) If “No” please go to Question #3 below. | [ ]  | Yes | [ ]  | No |
| a. | Is compliance with EN ISO 11137 latest version claimed | [ ]  | Yes | [ ]  | No |
| If “No” please explain: |  |
| [ ]  | Gamma  | [ ]  | E-Beam |
| b. | What Dose setting method(s) are used |
| [ ]  | VDMAX25 | [ ]  | Method 1 | [ ]  | Method 2 |
| 3 | Is moist heat used for Sterilisation of the device(s) If “No” please go to Question #4 below. | [ ]  | Yes | [ ]  | No |
| Is compliance with EN ISO 11138 latest version claimed | [ ]  | Yes | [ ]  | No |
| If “No” please explain |       |
| What cycle type used  | [ ]  | Pre-vac | [ ]  | Gravity | [ ]  | Other |
| Details if “Other” – |  |
|  | 4. | If one of the above methods is not used, please describe the method – (e.g. Dry heat, Aseptic Fill, Liquid Chemical, etc.) and list the standard(s) applied |       |

| **Section 9: Sterilisation** |
| --- |
| 9.2 Maintenance of Sterility over shelf life |
| 1. | Please define the shelf life/expiry date |       Years |
| 2. | Please confirm the number of sterilisation cycles that the device and packaging were subjected to prior to stability testing - |       |
| 3. | Please describe the preconditioning applied (eg. Ageing, transport etc): |       |
| 4. | Is compliance with EN ISO 11607 latest version claimed  | [ ]  | Yes | [ ]  | No |
| If “no” please justify: |  |
| 5. | If submitting Accelerated Aging data to support Shelf life, please confirm start date and expected completion date for real time Packaging studies |
|       |       |
| 6. | Please list and supply all relevant reports which substantiate Packaging shelf life –  |
|       |

| Section 10: BIOCOMPATIBILITY |
| --- |
| Please confirm the categorisation of the devices with respect to Body Contact and Duration of Contact in Table 6 below & the testing conducted in Table 7 |
| 1. | Is compliance with EN ISO 10993-1 latest version claimed | [ ]  | Yes | [ ]  | No |
| If “no” please justify: |       |
| 2. |

|  |
| --- |
| **Table 6a – Biocompatibility Categorisation : Body Contact** |
| **Surface-contacting devices** | **External communicating devices** | **Implant devices** |
| [ ]  | Skin | [ ]  | Blood path, indirect | [ ]  | Tissue/bone |
| [ ]  | Mucosal membranes | [ ]  | Tissue/bone/dentin | [ ]  | Blood |
| [ ]  | Breached/compromised surfaces | [ ]  | Circulating blood |  |

 |
| 3. |

|  |
| --- |
| **Table 6b – Duration of Contact** |
| [ ]  | Limited exposure(< 24hrs) | [ ]  | Prolonged exposure(>24hrs <30 days) | [ ]  | Permanent contact (>30 days) |

 |

| **Section 10: BIOCOMPATIBILITY** |
| --- |
| Please confirm the categorisation of the devices with respect to Body Contact and Duration of Contact in Table 6 below & the testing conducted in Table 7 |
| 4. |

| Table 7 – Tests considered/done |
| --- |
| Tests to be considered | ISO 10993 seriesYear | Test completed by | Report number | Date | Conclusion |
| Cytotoxicity | -5 :       |  |  |  |  |
| Sensitisation(Delayed type hypersensitivity) | -10 :       |  |  |  |  |
| Irritation or intra-cutaneous reactivity | -10 :       |  |  |  |  |
| Systemic toxicity (Acute)pyrogenicity | -11 :       |  |  |  |  |
| Sub-chronic toxicity (sub-acute toxicity) | -11 :       |  |  |  |  |
| Genotoxicitymutagenicity  | -3 :       |  |  |  |  |
| Implantation | -6 :       |  |  |  |  |
| Haemo-compatibility | -4 :       |  |  |  |  |
| Chronic toxicity | -11 :       |  |  |  |  |
| Carcinogenicity | -3 :       |  |  |  |  |
| Reproductive and developmental toxicity | -3 :       |  |  |  |  |
| Biodegradation | -9 :       |  |  |  |  |
| Toxicokinetic studies | -16 :       |  |  |  |  |
| Immunotoxicology | -20 :       |  |  |  |  |
| Other Tests |  |  |  |  |  |

 |
| 5. | Has testing been done on finished/sterilized device(s), or on materials that have been processed in the same manner, including sterilization | [ ]  | Yes | [ ]  | No |
| If “no” please justify: |       |
| 6. | Have biocompatibility test results been assessed and deemed acceptable by a competent individual? |
|       |

| Section 11: Medical Electrical (ME) Equipment & Systems, plus Software |
| --- |
| 1. | Is the product ME Equipment or System | [ ]  | Yes | [ ]  | No |
| **Please answer all questions below and complete Tables 8, 9 & 10****Please provide all relevant Test Reports, and EN 62304 Software Development Process & Validation Report, as well as Software Risk Assessment.** |
| 2. | Have the applicable requirements of EN 60601-1 latest version, including the mandatory risk assessment to EN 14971 been applied | [ ]  | Yes | [ ]  | No |
| If “No”, is a particular standard (60601-2-xx) applicable that refers to a prior 60601-1 (ex. 2nd edition)? | [ ]  | Yes | [ ]  | No |
| If “Yes” – please list all applicable “Part 2’s” in Table 9 below |
| If “No” – please provide rationale for not applying the latest version of EN 60601-1 – |
|       |
| 3. | Please list the document(s) submitted substantiating conformance to the edition of EN 60601-1 claimed – |
|  |       |
| Note – the electrical review will include a review of the document(s) in which conformance with all applicable EN 60601-1 requirements as well as EN 60601-2-x if applicable are tested. Please ensure the tester understands and is familiar with a comprehensive test report/checklist format addressing each applicable requirement. Abbreviated reports and summaries are NOT acceptable. |
| 4. | What is the expected Service Life of the device |       years |
| 5. | What is the Essential Performance of the device -  |       |
| 6. | Does the product incorporate Software/Firmware or meets theDefinition of Standalone Software per MEDDEV 2.1/6?  | [ ]  | Yes | [ ]  | No |
| If “Yes” Have the requirements of EN 62304, including the mandatory risk assessment to EN 14971 been applied in submitted software documents  | [ ]  | Yes | [ ]  | No |
| Version of Standard : |       |
| If not the latest version, please explain - |       |
| **7.** | Please provide the safety classification (A, B, C) and rationale for each software or firmware unit. |
|  | Please also provide all documentation to demonstrate compliance with EN 62304: as shown below |
|

|  |
| --- |
| **Table 8 – EN 62304 Compliance**  |
| **EN 62304 requirement** | **Class A** | **Class B** | **Class C** |
| 4.3 Software safety classification | X | X | X |
| 5.1 Software development plan | X | X | X |
| 5.2 Softwarerequirements | X | X (incl. RISK CONTROL measures) | X (incl. RISK CONTROL measures) |
| 5.3 SoftwareARCHITECTURAL design | N/A | X | X (incl. segregation for RISK CONTROL) |
| 5.4 Software detaileddesign | N/A | X | X (incl. detailed design of SOFTWARE UNIT & interfaces) |
| 5.5 SOFTWARE UNITimplementation | X | X(incl. verification & acceptance criteria) | X (incl. verification & acceptance criteria) |
| 5.6 Software integration& integration testing | N/A | X | X |
| 5.7 SOFTWARE SYSTEMtesting | N/A | X | X |
| 5.8 Software release (VERSION) | X | X (incl. ANOMALIES, how created, archive, repeatability) | X (incl. ANOMALIES, how created, archive, repeatability) |
| 6.1 Softwaremaintenance plan | X | X | X |
| 6.2 Problem &modification analysis | X | X (incl. analysis of CHANGE REQUESTS) | X (incl. analysis of CHANGE REQUESTS) |
| 6.3 Modificationimplementation | X | X | X |
| 7.1 Analysis of softwarecontributing to hazardoussituations | N/A | X | X |
| 7.2 RISK CONTROLmeasures | N/A | X | X |
| 7.3 VERIFICATION of RISK CONTROL measures | N/A | X | X |
| 7.4 RISK MANAGEMENT of software changes | X | X (incl. impact on existing RISK CONTROL measures) | X (incl. impact on existing RISK CONTROL measures) |
| 8 Software configurationManagement PROCESS | X | X | X |
| 9 Software problemresolution PROCESS | X | X | X |

 |

| **Section 11: Medical Electrical (ME) Equipment &** **Systems, plus Software** |
| --- |
| 7. |

|  |
| --- |
| Table 9 – Collateral Standards |
| **EN 60601-1-X** | **Year** | **Title** | **Applied/ Report** |
| EN 60601-1-2 |  | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests | [ ]  | Yes | [ ]  | No  |
| Report:       |
| EN 60601-1-3 |  | Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment | [ ]  | Yes | [ ]  | No  |
| Report:       |
| EN 60601-1-6 |  | Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability | [ ]  | Yes | [ ]  | No  |
| Report:       |
| EN 60601-1-8 |  | Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems | [ ]  | Yes | [ ]  | No  |
| Report:       |
| EN 60601-1-10 |  | Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers | [ ]  | Yes | [ ]  | No  |
| Report:       |
| EN 60601-1-11 |  | Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment) | [ ]  | Yes | [ ]  | No  |
| Report:       |
| For Collateral Standards not applied, please explain - |       |

 |

| **Section 11: Medical Electrical (ME) Equipment &** **Systems, plus Software** |
| --- |
| 1.8. |

|  |
| --- |
| **Table 10 – Particular Standards** |
| **EN 60601-2-X\*** | **Year** | **Title** | **Report** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| \*Also includes EN 80601-2-x.For Particular Standards not applied, please explain - |
|       |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Does the product incorporate SaMD or COTS  | [ ]  | Yes | [ ]  | No |
| If “Yes” Have the requirements of FDA Guidance on cybersecurity been applied | [ ]  | Yes | [ ]  | No |
| Version of Guidance : |  |

 |

| Section 12: DEVICE TESTING |
| --- |
| 12.1 – Device Design Testing |
| 1. | Please supply a Design Traceability Matrix or Design Input/ Output document and verify that the following have been included:* Design Input / User Need
* Specification for each Input
* Source of each specification
* Justification of the source (via use of a standard: Harmonised, Non-Harmonised ASTM, AAMI), predicate device testing, internally validated specification with clinical feedback, etc.)
* Design Output/ Documented Evidence
* Comment on whether D/I was met or not
 |
| 2. | Please supply all relevant Design Verification Testing (protocols and reports), substantiating the Design Outputs meet the Deisgn Inputs  |
|  |
| Note: NSAI shall not accept “For Information Only” data (FIO); all attributes tested shall have clinically relevant specifications. |
| Note: If safety and performance of the proposed device is being demonstrated via Equivalence to a predicate device, NSAI requires side-by-side verification data for the devices in question. |
| 3. | Please verify that the protocols and reports include:* Justified test parameters per relevant standards
* Acceptance Criteria
* Sample size methods, justification and documented source
* Justified deviations (if applicable)
 |
| If not, please justify:  |
|       |
| Please describe the design characteristics that address the interaction of the device surface with the body contact area |
|       |
| 4. | Please describe the functional testing that represents the device lot release criteria: |
|       |

| **Section 12: DEVICE TESTING** |
| --- |
| 12.2 – Device Stability |
| 1. | Please define the shelf life/expiry date -       years |
| 2. | Please confirm the number of sterilisation cycles that the packaged devices have undergone prior to stability analysis -       |
| 3. | Please outline the specific conditioning applied to the devices substantiating device stability :  |
|       |
| 4. | Were all device attributes assessed at the proposed shelf life? | [ ]  | Yes | [ ]  | No |
|  | If “No” please justify reason for omitting other attributes- |
|       |
| 5. | Confirm start date of real time Device studies.  |  |
| 6. | Please list all relevant reports which substantiate device shelf life |
|       |

| Section 13: Clinical Testing (Animal Model) |
| --- |
| 1. | Have acute/chronic animal studies been completed to substantiate the *in vivo* safety and/or performance of the device design  | [ ]  | Yes | [ ]  | No |
| If “No” please explain -  |
|       |
| 2. | Does the data provide detailed information on all studies in animal models which substantiate the stated intended use, i.e.: |
| * Study objectives
 | [ ]  |
| * Methodology
 | [ ]  |
| * Results, Analysis and Conclusions
 | [ ]  |
| * Rationale for selection of the model(s)
 | [ ]  |
| If “No” please explain- |       |
| 3. | Please indicate the document number(s) of all animal studies - |
|       |
| 4. | Please justify the Animal Model Used |
|       |
| 5 | Please provide summary data of the acute in vivo device performance against pre-defined requirements, and/or clearly define the location of the relevant data within each animal report- |
| 6. | Was the product design assessed in the animal studies equivalent to the device design subject of this submission | [ ]  | Yes | [ ]  | No |
| If “No” please explain -  |
|       |

| Section 14 – Clinical Performance (Human) |
| --- |
| 14.1 Clinical Evaluation |
| **Revisions to the MDD 93/42/EC by 2007/47/EC have implications for the clinical data & the evaluation of the data to be provided by Manufacturers to the Notified Body, to demonstrate the clinical safety & performance of the medical device.****Clinical data must always be documented for all medical device classifications.****MedDev 2.7.1 latest version provides guidance on the procedure to be adopted by the Manufacturer to evaluate clinical data.****Please supply a Clinical Evaluation Report to support the safe use of the device as per MedDev 2.7.1.** |
| 1. | Please provide the document number and location of the Clinical Evaluation Report (CER) - |       |
| Please submit the literature search protocol and full text articles |
| [ ]  | Literature search protocol |
| [ ]  | Full text of articles referenced in the CER. |
| If not please justify: |
|       |
| 2. | Does the CER comply with MedDev 2.7.1 | [ ]  | Yes | [ ]  | No |
| Version of MedDev used: |  |
| If “No” please justify -  |
|       |
| 3. | a. | Does the CER address the relevant risks of predicate device | [ ]  | Yes | [ ]  | No |
| If “No” please justify -  |
|       |
| b. | Does the CER address Post market surveillance and or PMCF ie. Registry or study (reference MED DEV 2.12 /2 )  | [ ]  | Yes | [ ]  | No |
| c. | How often is the CER updated with data from the post market surveillance(reference Annex X 93/42/EEC  |
| How often is the CER updated?      |
| Please provide justification for the frequency of update      |

| **Section 14 – Clinical Performance (Human)** |
| --- |
| 14.1 Clinical Evaluation |
| 3. |  |
| Please identify the individual(s) who performed the clinical evaluation - |
|       |
| Is their CV included? | [ ]  | Yes | [ ]  | No |
| Is a declaration of interest of the evaluators included | [ ]  | Yes | [ ]  | No |
| If “No” please explain - |
|       |
| Please provide justification of the choice of evaluator(s) - |
|       |
| 4. | Has a clinical investigation been performed to demonstrate the safety and performance of the device | [ ]  | Yes | [ ]  | No |
|  | If “No” please explain -  |
|  |       |
| 5. | For this device : |
|  | a. | Are any further clinical investigations planned | [ ]  | Yes | [ ]  | No |
|  | b. | Are any further clinical investigations on-going | [ ]  | Yes | [ ]  | No |
|  | c. | Are any other relevant clinical investigations completed | [ ]  | Yes | [ ]  | No |
|  | d. | How often is the CER updated with data from the post market surveillance(reference Annex X 93/42/EEC  |
|  | If “Yes” please provide additional information including study identifier and status |
|  |       |
|  | **(note** – not limited to EU S&P studies / Investigations, i.e. include reference to Other Geographical Reg Requirements, studies/investigations for reimbursement purposes, etc) |
| 6. | For clinical investigations please submit the following: |
|  | [ ]  | Letter of no objection from Competent Authority(s) (CAs) or other regulatory agency(s) as appropriate |
|  | [ ]  | Clinical investigation plan and amendments for which no grounds for objection were raised |
|  | [ ]  | Ethics committee opinion(s) and comments arising from their review |
|  | [ ]  | Signed and dated final report (signed by the sponsor, the co-ordinating clinical investigator – if appointed – and principal investigator at each site). |
|  | If not please justify - |
|  |       |
| 7. | Where no clinical investigations have been carried out and where equivalence is being claimed, completed form GRF 25-28, (equivalence route clinical evaluation) |

| Section 15 – Critical process details |
| --- |
| Please provide a documented overview, including a process flow chart, of:* Assembly
* Special processes
* Critical materials, components
* Packaging of finished medical device
* Final and any in-process product testing
 |
| Document reference: |       |
| Please provide evidence of completed process validations to support the transfer to manufacturing (This evidence may be in the form of a completed validation master plan/report or similar). |
|       |

| Section 16 – ADDITIONAL INFORMATION |
| --- |
| **Please use this section to document any additional information not already covered.** |
| If any of the APPENDICES apply, please complete Table 12. |
|       |
|

|  |
| --- |
| **Table 12 – Applicable Appendices** |
| **Directive** | **Description – Devices containing** | **Applicable** |
| 722/2012/EU | Tissue of Animal Origin | [ ]  | No |
| [ ]  | Yes: Complete Appendix A |
| 2000/70/EC | Human Blood Derivative(s) | [ ]  | No |
| [ ]  | Yes: Complete Appendix B |
| 2001/83/EC | Medicinal Substances | [ ]  | No |
| [ ]  | Yes: Complete Appendix C |

 |



**Medical Devices**

# Appendix A

#### Medical Devices incorporating tissues of animal origin,covered by the TSE Directive 722/2012 EU only

## [Submission](#aaNSAI_TableOfContents) Details

**Please tick all that apply:**

|  |  |  |  |
| --- | --- | --- | --- |
| [ ]  | Class 3 |  |  |
| [ ]  | TSE |  |  |
|  |  |  |  |
| [ ]  | Fast Track (expedited) |  |  |
|  |
| **Directive(s) that apply:** | **NSAI File Number** |
| [ ]  | MDD (93/42/EEC)  | 252.     /      |
| [ ]  | TSE |

|  |
| --- |
| Please complete the table below: |
| **Appendix A Table 1** |
| Starting tissue used |       |
| Species Used |       |
| Geographical sourcing |       |
| Veterinary controls |       |
| Feeding restrictions |       |
| Evidence of compliance with regulation1609 (where the raw material or intermediates are imported or processed in the EU) |       |
| GBR rating of tissue |       |
| Details of collagen, tallow or gelatine used.  |       |
| Details of source establishments |       |
| Scope of Site(s): |       |
| EDQM Certificate (Yes / No) | x | # :  |        | Expiry Date |       |
| (please supply copy) |
| If no valid EDQM Certificate held, please supply: |
| Details of harvesting of the animal tissue |
| TSE infectious agents inactivation steps |
| TSE infectious agents clearance validation |
| Source establishments |
| Copy of compliance to Regulations1609 |
| Details of the source of tissue - geographical location, open/closed herds, feeds, pre and post mortem inspection. |

|  |
| --- |
| 1. Description of Production Steps |
| Please provide details of all production steps in which the animal tissue is present including a description of the key elements adopted to minimise the risk of infection: |
|       |

|  |
| --- |
| 2. Auditing Source Establishments |
| Please provide information on the auditing of source establishments &/or third party supplier for the animal material used by the medical device manufacturer including details of feeding restrictions: |
|       |

|  |
| --- |
| 1. **Harvesting and TSE infectious agents inactivation of the animal tissue**
 |
| Please provide details on the harvesting of the animal tissue and relevant TSE infectious agents inactivation steps performed on the animal tissue prior to its incorporation into the device. The TSE infectious agents clearance validation study of the animal tissue, protocol and report, should also be supplied – conformity to EN ISO 22442-1, -2, & -3 must be demonstrated: |
|       |



**Medical Devices**

# Appendix B

#### Medical Devices incorporating Human Blood

#### Derivative only

**Please tick all that apply:**

|  |  |  |  |
| --- | --- | --- | --- |
| [ ]  | Class 3 |  |  |
| [ ]  | Human Blood |  |  |
|  |  |  |  |
| [ ]  | Transfer (from another NB) |  |  |
| [ ]  | Modular (partial application) |  |  |
|  |  |  |  |
| [ ]  | Fast Track (expedited) |  |  |
|  |
| PO Number |       |
|  |
| **Directive(s) that apply:** | **NSAI File Number** |
| [ ]  | MDD (93/42/EEC)  | 252.     /      |
| [ ]  | Human Blood |  |

|  |
| --- |
| **Please compile the technical dossiers in the volumes detailed below:**  |
| *Volume 1: Completed EMEA application form (Doc. Ref. EMEA / CHMP/ 434094/ 2005)* |
| *Volume 2: Product Information and Labelling* |
| *Volume 3: Appendix II (ref Doc. Ref. EMEA/CHMP/401993/2005)* |
| *Volume 4: Quality Summary of the ancillary medicinal substance as integrated into the medical device in accordance with MEDDEV 2.1/3 rev 2, section B2, a – q.* |
| *Volume 5: Quality Summary of the ancillary medicinal substance in accordance with Module 2.3 of*  |
| *Volume 2B, CTD of the Notice to Applicants (Eudralex).* |
| *Volume 6: Tabular summaries for non-clinical and clinical studies.* |
| *Volume 7: Quality, non-clinical and clinical documentation in accordance with MEDDEV 2.1/3 rev 2 for the ancillary medicinal substance as integrated into the medical device section B2, a – q.* |
| *Volume 8: Relevant parts of Module 3 of Volume 2B, CTD of the Notice to Applicants for the ancillary medicinal substance and a copy of the latest PMF annual update.* |
| NOTE - Please be advised that following review of the application by the NSAI, amendments may be requested to the technical dossiers prior to their submission to the EMEA.The number of hard and soft copies of the technical dossiers required by the EMEA will vary depending on the appointed Rapporteurs, it is the responsibility of the Medical Device Manufacturer to prepare these as directed by the NSAI.Please complete the table below: |

|  |  |
| --- | --- |
| 1. | APPENDIX B Table 1 |
|  |

|  |
| --- |
| Appendix B Table 1 |
| Derivative(s) Supplier: |       |
| Supplier Address: |       |
| Test laboratory used: |       |
| Laboratory Address: |       |
| Laboratory Approvals: |       |
| Contract company used for bioavailability or bioequivalence trails |       |
| Contact person in the EEA for product recall and defects |       |
| Approval Certs for above sites: |       |
| EMEA Scientific Opinion: |       |

 |

|  |
| --- |
| 2. Details of human blood derivative(s) used |
| 2.1 | Please provide a detailed description of derivative. The quantities of product derived from human blood should be expressed by mass or international units of biological activity appropriate to the product concerned. |
|  |       |
| 2.2 | Does the Human Blood Derivative has a Ph. Eur. Certificate of Suitability? | [ ]  | Yes | [ ]  | No |
| If so, please supply a letter of access to the related Drug Master File or a copy of the Ph. Eur. Certificate of Suitability for the component. |
| Please supply PMF Master Files certificates for the human blood derivative (this should include the original certificate and the latest annual up-date) |

|  |
| --- |
| 1. **Justification for use of human blood derivatives**
 |
| Please provide an in-dept rational justifying the use of tissue in specific application, including a comparison with materials sourced from non-human derivatives, and expected clinical benefit. |
|       |

|  |
| --- |
| 1. **Verification of Usefulness of the Device**
 |
| In addition to the justification above, please provide a review of currently available devices & technologies, confirming medical necessity based on an expert clinician recommendation & review: |
|       |

|  |
| --- |
| 1. **Human Blood Derivative Manufacture**
 |
| Please supply: |
| [ ]  | A copy of the Manufacturing Authorisation for the Ancillary Medicinal Substance containing Human Blood Derivatives. |
| [ ]  | A statement from the Competent Authority which carried out the inspection of the Human Blood Derivative manufacturing sites. |
| [ ]  | Written confirmation from the manufacturer of the ancillary active substance that the applicant will be informed in the case of any modification of the manufacturing process or specifications. |
| [ ]  | Written confirmation from the manufacturer of the human blood derivative to inform the medical device manufacturer in the case of any modifications to the PMF. |
| [ ]  | Written confirmation from the manufacturer of the human blood derivative to complete look back procedures in the event of product recalls. |

|  |
| --- |
| 1. **Human Blood Derivative Supplier(s), Collection and Controls**
 |
| Please complete the table below: |
|

|  |
| --- |
| Appendix B Table 2 |
| Details on the control of suppliers |  |
| Source of blood/donor control |  |
| Nature of donation – pooled or single donation |  |
| Details on the collection of source materials |  |

 |

|  |
| --- |
| 1. **Derivative Manufacturing steps**
 |
| Please outline the derivative manufacturing steps |
|       |

|  |
| --- |
| 1. **Inactivation steps**
 |
| Please document the production steps used to minimise risk of infection and provide the necessary viral clearance validation studies: |
|       |

|  |
| --- |
| 1. **Laboratory Test Details – derivative**
 |
| Please provide details of the laboratory tests and also provide the necessary validation(s): |
|       |

|  |
| --- |
| 1. **Quality Control of derivative**
 |
| Please provide details of the in-process & final test procedures: |
|       |

|  |
| --- |
| 1. **Procedures for batch release of derivative**
 |
| Please provide details of the batch release procedures for derivative(s): |
|       |

|  |
| --- |
| 1. **Derivative Storage & Stability**
 |
|  **(in addition to the Device stability covered previously)** |
| Please confirm the shelf life of the derivative: |       |
| Please provide details of the storage & transport requirements along with stability studies and validation for the derivative: |
|       |

|  |
| --- |
| 1. **Device Manufacturing Steps**
 |
| Please provide details of the manufacturing steps & any relevant procedures for the device using derivativeIs) along with the relevant validation of the effect on quality & viral safety on the finished device: |
|       |

|  |
| --- |
| 1. **Device Testing & Quality Control**
 |
| Please provide details of the device in-process and final test(s) & any relevant procedures: |
|       |

|  |
| --- |
| 1. **Device Batch Release**
 |
| Please provide copies of the batch release procedures for finished devices: |
|       |

|  |
| --- |
| 1. **Packaging components**
 |
| Please provide details of the packaging components including a description from which the material is constructed using current standard terms – European Pharmacopeia where applicable: |
|       |

|  |
| --- |
| 1. **Previous Existing Legislation - additional**
 |
| Please provide details of the applications for the same derivative both in and out of the EEA including those which are authorised, pending and refused.If the device does have other applications for the same derivative please provide details of the country, the trade name, date of submission/suspension and the reason for suspension where appropriate: |
|       |

|  |
| --- |
| 1. **Risk analysis – additional**
 |
| Please proved additional risks pertaining to the use of Human Blood |
|       |

|  |
| --- |
| 1. **Labelling and IFU - additional**
 |
| Please proved additional labelling pertaining to the use of Human Blood  |
|       |

 

**Medical Devices**

# Appendix C

**Medical Devices incorporating Medicinal Substance only**

## [Submission](#aaNSAI_TableOfContents) Details

**Please tick all that apply:**

|  |  |  |  |
| --- | --- | --- | --- |
|  [ ]  | Class 3 |  |  |
| [ ]  | Medicinal Substance |  |  |
|  |  |  |  |
| [ ]  | Transfer (from another NB) |  |  |
| [ ]  | Modular (partial application) |  |  |
|  |  |  |  |
| [ ]  | Fast Track (expedited) |  |  |
|  |
| **Directive(s) that apply:** | **NSAI File Number** |
| [ ]  | MDD (93/42/EEC)  | 252.     /      |
| [ ]  | Medicinal Substances |

|  |
| --- |
| **Please provide a dossier detailing the medicinal substance prepared in compliance with MEDDEV 2.1.3 section B3 (A-Q).**Please complete the table below: |
| 1. |

|  |
| --- |
| Appendix C Table 1 |
| Name of Medicinal Substance |       |
| Name & address of Medicinal Substance manufacturer |       |
| Name & address of Medicinal substance supplier(s) |       |
| Function of Medicinal Substance within medical device |       |
| copies of the signed/dated agreements between the company and each supplier;  |  |
| Confirmation that all active agents and excipients (as required by the EMA) disclosed on the product labelling (provide evidence) |  |
| EDQM Certificate for Medicinal Substance (Yes / No) |       |
| Note – NSAI Certificate will not exceed the expiration date of the EDQM certificate |

 |
| **If no EDQM certificate is available, please supply the drug master file for the medicinal substance***certificates of analysis/certificate of compliance;**•         copies of the MSDS (Material Safety Data Sheets);**•         copies of the current ISO/GMP or other quality certification;* *•         copies of the audit reports from the most recent supplier audits conducted by the company or another recognized organizations (e.g., ANSM, FDA, etc.;*  |

|  |
| --- |
| **2.** **Qualitative and quantitative particulars of the****constituents** |
| Please provide a description of the substance and the amount (giving a range where appropriate) of the medicinal substance incorporated into each medical device.If the substance is modified during its incorporation into the device, please provide relevant information: |
|       |

|  |
| --- |
| 3. Description of method of manufacture |
| In addition to the overall description supplied, please provide details of the incorporation of the medicinal substance into each medical device.If the medicinal substance is altered in any way prior to its inclusion into the device, please provide relevant information*:* |
|       |

|  |
| --- |
| 4. Control of starting materials |
| Please provide the specification for the medicinal substance. Where applicable, reference shall be to the European Pharmacopoeia or in the absence of an EP monograph to a national pharmacopoeia of one of the Member States. If no monograph is available from the Member States reference may be to other national monographs or to the manufacturer's specification and methods of analysis.For new active substances and certain known substances additional information will be required which may be provided in the form of a Drug Master File. The guideline "Requirements in relation to active substances"(1) may be of assistance in providing circumstances where reference to a Pharmacopoeia monograph may need to be supplemented by further information: |
|       |

|  |
| --- |
| 5. Control of tests carried out at intermediate stages of the manufacturing process of the medical device |
| If necessary, please supply information regarding the control of tests carried out at intermediate stages of the manufacturing process. |
|       |

|  |
| --- |
| 6. Control tests on finished products |
| Please supply details of the qualitative and quantitative tests carried out to control the medicinal substance in the device. |
|       |

|  |
| --- |
| 7. Toxicity |
| Please provide reference to the known toxicological profile of the medicinal substance.In the case of new active substances, the results of the toxicity tests should be supplied |
|       |

|  |
| --- |
| 8. Reproductive Function |
| Please provide reference to the known profile in relation to reproductive function, of the medicinal substance.In the case of new active substances, the results of the appropriate tests should be supplied |
|       |

|  |
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| 9. Embryo/foetal and perinatal Toxicity |
| Please provide reference to the known embryo/foetal & perinatal toxicological profile of the medicinal substance.In the case of new active substances, the results of the toxicity tests should be supplied |
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| 10. Mutagenic potential |
| Please provide reference to the known mutagenic potential of the medicinal substance.In the case of new active substances, the results of the relevant tests should be supplied |
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| 11. Carcinogenicity potential |
| Please provide data on the carcinogenicity potential of the medicinal substance. |
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| 12. Pharmacodynamics |
| Please provide details on the pharmacokinetics – addressing some or all of the points below as appropriate:description of the pattern of local and systemic exposure to the medicinal substance, where the level of exposure fluctuates, the maximum level and duration of exposure should be considered, where it is considered possible that potential levels of systemic exposure may present a safety concern, maximum peak plasma concentration should be established, taking due consideration of individual variability, new active substances will require information on the release from the device, and, if relevant, its subsequent distribution and elimination.  |
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| 13. Local Tolerance |
| Please provide details on the local tolerance of the medicinal substance. |
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| 14. Risk analysis - additional |
| Please provide additional risk analysis pertaining to the use of TSE. |
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| 15. Stability - additional |
| Please provide additional stability data pertaining to the use of TSE. |
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