

**Medical Devices**

# Re-Certification Application Form

**Applicant Information**

**Please tick all that apply:**

|  |  |
| --- | --- |
| [ ]  | Re-Certification Review |
|  |
| PO Number |       |
|  |  |
| [ ]  | Fast Track (expedited) if <90 days from Certificate expiry |
|  |
| **Directive(s) that apply:** | **NSAI File Number** |
| [ ]  | MDD (93/42/EEC)  | 252.     /      |
| [ ]  | AIMD (90/385/EEC) | 253.     /      |
| [ ]  | TSE (2012/722/EU) |  |
| [ ]  | Class 1S&M |  |
| [ ]  | Class 2A &2B non-implantable |  |
| [ ]  | Class 2B implantable, Class 3, AIMD |  |
| If OBLs apply to this product, please state the relevant product families below: |
|  |      / |      ; |      / |      ; |      / |       |

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

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| DECLARATION(S) BY APPLICANT |
| In making this application we declare:In signing this form, the manufacturer is verifying that the requirements of the Directive have been applied in full during the re-certification process.* 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: |  |

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| 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 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 in 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 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 any sites in Table 1 NOT registered with NSAI |
|  | Type Examination Certificate if required |
|  | Declaration of Conformity |
|  | Stability data – if necessary |
|  | Harmonised Standards |
|  | Labelling & IFU – May be Drafts |
|  | Risk Management Documentation |
|  | Performance/Complaint Analysis |
|  | Sterilisation Validation(s) – if sterile/intended to be sterilised |
|  | Clinical investigation(s) report(s) and supporting documents per MEDDEV 2.7.1 |
|  | Clinical Evaluation Report(s) per MEDDEV 2.7.1 |
|  | Clinical Evaluation Procedure  |
|  | Literature Search Protocol |
|  | Literature Search Report |
|  | Clinical investigation protocol and report if any clinical investigation has been undertaken in the 3 year period |
|  | Additional Information (see below) |
| **For Tissue of Animal Origin falling under TSE Directive 2012/722/EU** |
|  | Please complete Section 7, table 6 |
| **For Human Blood Derivatives** |
|  | Please complete Section 7, table 6 |
| **For Medicinal Substances** |
|  | Please complete Section 7, table 6 |

| 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 :  |  |
| **MDD ONLY:** |
| Class | [ ]   | III  | [ ]   | IIb  | [ ]   | IIa  | [ ]  | Is  | [ ]   | Im | Rule(s) |  |
| Rationale |  |
| Conformity Assessment | Annex | [ ]  | II | [ ]  | V (+VII) | [ ]  | V + III | [ ]  | VI |
| Full QA | Prodn QA | +Type testing | Product QA |
| **AIMD ONLY:** |
| Conformity Assessment | Annex | [ ]  | 2 | Annex | [ ]  | 3 + 5 |
| Full QA | Prodn QA + Type Testing |
| 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: PRODUCT STABILITY AND ON-GOING TESTING |
| --- |
| 1. | Does the product have a shelf life | [ ]  | Yes | [ ]  | No |
| 2 | Please define the shelf life (include all sub families) |
|  |       |
| 3. | please provide an update and the most recent data point on any real time aging activities currently underway, or completed during the current product certification cycle:  |
|  |       |

| Section 3: Harmonised Standards |
| --- |
| 1. | In the cases where there have been changes or updates to the technical content/requirement of the standard, please: |
| 1. List any updated Harmonized Standards in Table 3 below and
 |
| 1. Provide evidence of compliance to the new standard, addressing how the revised standard has been considered and implemented.
 |
| **For MDD see**<http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/medical-devices/index_en.htm> |
| **For AIMD see**<http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/implantable-medical-devices/index_en.htm> |
|

|  |  |  |  |
| --- | --- | --- | --- |
| Harmonized Standard | Year | ComplianceYes/No | Evidence of Compliance  |
| EN ISO 10993-1 | 2009 | Yes | Report # x, pg x, para. X |
| EN ISO 14971 | 2012 | Yes | Report # x, pg x, para. X |
| IEC 60601-1, 3rd Edition | 2006 | Yes | Report # |

 |
|

| **TABLE 3 – Compliance with updated Harmonized Standards Only** |
| --- |
| Harmonized Standard | Year | ComplianceYes/No | Evidence of Compliance (e.g. Delta or new report) |
|  |  |  |  |
|  |  |  |
|  |  |  |

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| Section 4: Performance / Complaint analysis |
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| **Please provide a summary analysis of product complaints and Vigilance Reportable Incidents as outlined below** |
| **A.** | **COMPLAINTS;** |
|  | 1. | Time period of the complaint data being provided – |
| [ ]  | Last 3yrs – |
| [ ]  | Lifetime of the device (Please define-     ) |
| 2. | Summary |
|  |

| Total no. units placed on the market\* |  |
| --- | --- |
| Total no. of complaints |  |
| Total no. of reportable events (worldwide) |  |
| \*including devices used on patients as part of a preference study, trial, etc. |

 |
| 3. | Please provide an analysis of complaint data over the stated period of time, in either graphic or table form, summarizing types of complaints, (e.g. performance related, clinical user related, labeling issue, off-label use, product misuse, complaint justified / non-justified) with quantity and % total sales. |
| 4. | Are there currently any regulatory actions, or pending regulatory actions against this device (e.g. recalls, withdrawals, field safety notices, consent decrees, refusals to approve) | [ ]  | Yes | [ ]  | No |
|  | If “Yes” please describe |
|       |
| 5. | Please provide details of any OEM/OBL performance issues: |
|  |       |
| **B.** | **VIGILENCE REPORTS:** |
|  | 6. | Summary supplied of all Vigilance Report(s) submitted to EU Competent Authorities during the current product certification cycle – (see table 5) | [ ]  | YES  |
|  | 7. | Has this product been the subject of product recalls or Incident Reports in other Regulatory geographies outside EU? | [ ]  | Yes | [ ]  | No |
|  |  | If “yes”, please summarize and provide details – see table 5 |
|  | 8. | Has NSAI received all the Vigilance Report(s)  | [ ]  | Yes | [ ]  | No |
| If “Yes” please provide the relevant Unique Identifier number(s) - |
|       |
| If “No” please: |
| a. | Justify       |
| b. | If applicable, please submit a copy of the Vigilance Report(s) submitted to EU Competent Authorities along with the completed NSAI Vigilance Form located at [<http://www.nsaiinc.com/services/MedicalDevice> -“Vigilance Reporting”] to vigilance@nsai.ie  |
| **C.** | **CORRECTIVE ACTIONS:** |
| 9. | In the table below, please provide a summary of corrective actions implemented as a result of vigilance or complaint trends.  |
| 10 | Please summarize all global Vigilance issues that fulfill the European Reporting requirements in the following/similar format: |
|  |

|  |
| --- |
| **Table 4 Vigilance Summary Table:** |
| **Unique ID 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 5: Sterilisation |
| --- |
| 1. | Is the product provided Sterile? | [ ]  | Yes | [ ]  | No |
|  | **Please provide the latest Sterilization Revalidation** **protocol(s) & report(s)****For Irradiation, please supply the last year’s Dose Audits.****(i.e. all from last 12 months)** |
|  |

| **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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Include lines and cycles |
| 2. | If EtO is utilized for Sterilization, please categorize the device according to the duration of contact below, and provide data in support of the most recently completed residual testing |
|  |  | [ ]  | A – Limited Exposure |
| [ ]  | B – Prolonged Exposure |
| [ ]  | C – Permanent Contact |

| Section 6 – CLINICAL Performance (Human) |
| --- |
| **Please provide and updated Clinical Evaluation Report to support the on-going safety and performance of the device as per MEDDEV 2.7.1** |
| 1. | Does the CER comply with MEDDEV 2.7.1 | [ ]  | Yes | [ ]  | No |
| If “No” please explain -  |
|       |
| 2. | a. | Does the CER address the relative risks of predicate devices | [ ]  | 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 ) |
|  |       |
| 3. | Please identify the individual(s) who performed the clinical evaluation - |
|       |
| Has a suitably qualified individual been involved in the review of data and the determination of clinical safety and performance | [ ]  | Yes | [ ]  | No |
| Is their CV included | [ ]  | Yes | [ ]  | No |
| If “No” please justify - |
|       |
| Please provide justification of the choice of evaluator(s) –by considering the following  |
| * the device technology and its application;
* research methodology (clinical investigation design and biostatistics); and
* diagnosis and management of the conditions intended to be treated or diagnosed by the device.
 |
|  |       |
| 4. | For this device: |
|  | a. | Are any further clinical investigations planned  | [ ]  | Yes | [ ]  | No |
| b. | Are any clinical investigations on-going  | [ ]  | Yes | [ ]  | No |
| c. | Have any additional clinical investigations been completed during the current product certification cycle? |  |  |  |  |
| If “Yes” please provide additional information and status (per MEDDEV 2.7.1) |
| * investigation report signed and dated
* investigation protocol
* CA(s) letter of no objection or other regulatory bodies approval of protocol
* Ethics Committee approval letter(s)
 |

| Section 7 Additional Information |
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| **Please use this section to document any additional information not already covered.** |
| Please complete Table 6.

|  |
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| **Table 6** |
| **Directive** | **Description – Devices containing** | **Applicable** |
| 2012/722/EU | Tissue of Animal Origin | [ ]  | No | [ ]  | Yes |
| 2000/70/EC | Human Blood Derivative(s) | [ ]  | No | [ ]  | Yes |
| 2001/83/EC | Medicinal Substances | [ ]  | No | [ ]  | Yes |

 |
| 1. | **Devices containing Tissue of Animal Origin falling under 2012/722/EU** |
| EDQM Cert # |       |
| EDQM Cert expiry |       |
| Any change in GBR rating | [ ]  | Yes | [ ]  | No |
| if Yes, please comment: |  |  |  |  |
|       |  |  |  |  |
| 2. | **Devices containing Human Blood Derivatives under 2000/70/EC** |
| EDQM Cert # |       |
| EDQM Cert expiry |       |
| Justification for continued use of human blood derivative(s) |
|       |
| 3. | **Devices containing Medicinal Substances under 2001/83/EC** |
|  | Status of Drug Master File |       |