

**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** | | |
|  | IVD Annex II List B | | | | | | 304.     / | | |
|  | IVD Self-Test | | | | | | 304.     / | | |
|  | Transfer (from another NB) | | | | | |  | | |
|  |  | | | | | |  | | |
|  |  | | | | | |  | | |
| If OBLs apply to this product, please state the relevant product families below: | | | | | | | | | |
|  | / | | | ; | / | ; | | / |  |

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

Table of Contents

[Re-certification application form 1](#_Toc489430883)

[Declaration(s) by applicant 3](#_Toc489430884)

[Instructions 4](#_Toc489430885)

[Applicants’ submission checklist 5](#_Toc489430886)

[Section 1: Manufacturer and product details 6](#_Toc489430887)

[Section 2: Description of device 7](#_Toc489430888)

[Section 3: Intended use of the device 8](#_Toc489430889)

[Section 4: Substantial Changes 9](#_Toc489430890)

[Section 5: Product Stability and on-going testing 10](#_Toc489430891)

[Section 6: Harmonised Standards 11](#_Toc489430892)

[Section7: Performance/Complaint/Vigilance 12](#_Toc489430893)

[Section 8: Risk management 14](#_Toc489430895)

[Section 9: Sterilisation 15](#_Toc489430896)

[Section 10: Performance evaluation 16](#_Toc489430897)

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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** | | | | | | |
| Signed  on behalf of the Manufacturer: | |  | | Date: | |  |
| Name (please print): | |  | | | | |
| Position / Title: | |  | | | | |
| Contact person  (if different to Manufacturer): | |  | | | | |
| e-mail: |  | | Phone: | |  | |

|  |
| --- |
| 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. |

|  |  |
| --- | --- |
| 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 |
|  | Performance/Complaint Analysis |
|  | Sterilisation Validation(s) – if sterile/intended to be sterilised |
|  | Risk Management Report |
|  | Risk Management Protocol |
|  | Performance Evaluation Report |
|  | Any Additional Information |

| 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 applicable.: | | | | | |  | | |
| Sterilization Site(s) if applicable.: | | | | | |  | | |
| Scope of Site(s):  (i.e. as shown on the QMS cert) | | | | | |  | | |
| Name and address of EU Authorized 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: | | | | | | |  |
|  | | | | | | | | |
| Type of IVD in this Product Family | |  | Annex II List B | |  | | Self Test IVDs not covered by Annex II | |
| Conformity Assessment Route | |  | | | | | | |
| Rationale | |  | | | | | | |
| Date of this application  (i.e. date of Declaration of Applicant): | | | |  | | | | |

| SECTION 2: DESCRIPTION OF DEVICE | | | |
| --- | --- | --- | --- |
| Please provide a full description of the device which demonstrates that the product is covered under Directive 98/79/EC: | | | |
| Device Description: | | | |
| Please complete the Table below, providing a full and up-to-date list of the current model numbers and descriptions related to this review  *If the Declaration of Conformity is being used (instead of completing Table 2), please make sure that the WORD version is supplied.* | | | |
| Product Family Information | | | |
| Sub-Family | Model/Catalogue Number | Description | Class |
|  |  |  |  |
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| SECTION 3: INTENDED USE OF THE DEVICE | |
| --- | --- |
|  | Please Provide the most recent version of IFU and product labelling for review |
| 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: |
|  |  |
| 4 | List any Changes to Labelling since the previous 3 year review and provide the amendment number submitted to NSAI. |
|  |  |

| SECTION 4: Substantial Changes Please Provide a complete listing of all substantial changes made during the current product certification cycle | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| 1. | Products affected and amendment: | | | | | |
|  | | | | | |
| 2. | Changes to technical documentation:  Are there any changes to the technical documentation that apply to the criteria listed below: | | | | | |
| Changes to | Yes | No | n/a | Briefly Describe | Report Number |
| Buffers |  |  |  |  |  |
| Electrolytes (Na+, Ca++, etc.) |  |  |  |  |  |
| Proteins/Enzymes (e.g., Recombinant, Activity, Affinity, Purity, etc.) |  |  |  |  |  |
| Additives/Stabilizers (e.g., glycerol, 2-mercaptoethanol, etc.) |  |  |  |  |  |
| Reference Standards (medicinal agent, antibody, protein, etc.) |  |  |  |  |  |
| Accessories to IVDs (e.g., pre-processing of biological samples, etc.) |  |  |  |  |  |
| Packaging (vials, etc.) |  |  |  |  |  |
| Software |  |  |  |  |  |
| Instruments/Hardware |  |  |  |  |  |
| Operating Systems |  |  |  |  |  |
| Subcontractors/Suppliers |  |  |  |  |  |
| Others |  |  |  |  |  |

| SECTION 5: 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 define the in-use stability if applicable | | | | |
|  | | | | |
| 4 | Please define the re-constitution stability if applicable | | | | |
|  | | | | |
| 5 | Please define the Open Vial/Bottle stability if applicable | | | | |
|  | | | | |
| 6 | Please define the Shipping/ Transport stability including duration of transport and expected transport temperatures and humidity. | | | | |
|  | | | | |
| 7 | 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: | | | | |
|  | | | | |
| 8 | Is regular monitoring of the stability of the IVD reagent already on the market completed  Yes  No | | | | |
| If Yes-Provide data and summary | | | | |
| If no -Please provide Rationale | | | | |

| Section 6: 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 IVDD see**  https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/iv-diagnostic-medical-devices\_en | | | |
| Harmonised Standard | Year | Compliance Yes/No | Evidence of compliance |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
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| Section7: Performance/Complaint/VIGILANCErEPORTS/Trend analysis | | | | | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Please provide a summary analysis of product complaints and Vigilance Reportable Incidents as outlined below | | | | | | | | | | | | | | |
| **A** | **COMPLAINTS;** | | | | | | | | | | | | | |
| 1. Is the device commercialized | | | | Yes | | | No | | | | | | |
| If “No” please explain: | | | | | | | | | | | | | |
| 1. Time period of the complaint data being provided – | | | | | | | | | | | | | |
| Last 3yrs – | | | | | | | | | | | | | |
| Lifetime of the device (Please define-     ) | | | | | | | | | | | | | |
| 1. Total Unit Sales | | | | | | | | | | | | | |
| 1. Total Number of complaints | | | | | | | | | | | | | |
| 1. Total number of confirmed complaints | | | | | | | | | | | | | |
| 1. Total number of Reportable incidents | | | | | | | | | | | | | |
| 1. 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 | | | | | | | | | | | | | |
| 1. Please provide data on up-to-date QC / Production trends | | | | | | | | | | | | | |
| **B.** | **VIGILENCE REPORTS:** | | | | | | | | | | | | | |
| 1. Summary supplied of all Vigilance Report(s) submitted to EU Competent Authorities during the current product certification cycle – (see vigilance summary table below) | | | | | | | | | | |  | YES | |
| 1. Has this product been the subject of product recalls or Incident Reports in other Regulatory geographies outside EU?   If “yes”, please summarize and provide details – see vigilance summary table below | | | | | | | |  | Yes | |  | No | |
| 1. Has NSAI received all the Vigilance Report(s) | | | | | | | |  | Yes | |  | No | |
| If “Yes” please provide the relevant Unique Identifier number(s) - | | | | | | | | | | | | | |
| If “No” please:  Justify    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:** | | | | | | | | | | | | | |
| 12. | In the table below, please provide a summary of corrective actions implemented as a result of vigilance or complaint trends. | | | | | | | | | | | | |
| 13. | Please summarize all global Vigilance issues that fulfil the European Reporting requirements in the following/similar format:  Note: Please supply this table as an attachment to the submission | | | | | | | | | | | | |
| Vigilance Summary Table: | | | | | | | | | | | | |
| Unique ID No: | | Competent Authority | Details of Investigation | | Root Cause | CAPA Raised - Y/N & Details | | | | Status | | |
|  | |  |  | |  |  | | | |  | | |
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| Section 8: Risk Management | | | | | |
| --- | --- | --- | --- | --- | --- |
| Please Provide the current Risk Management Plan/Report and most recently completed Risk Analysis, including a signed and dated conclusion regarding residual/remaining risks.  Please provide the risk management procedure.  If applicable please ensure to include relevant risk analysis for IVD Medical equipment and software. | | | | | |
| **1.** | Is Compliance being claimed to EN ISO 14971: 2012 |  | Yes |  | No |
| **2.** | Please indicate which of the Multifunctional team provided the clinical output-i.e. risks associated with the clinical use of the device | | | | |
|  | | | | |
| **3.** | Please provide the document number of the Risk Analysis Matrix / Risk assessment summary matrix/documents and location within the technical file supplied - | | | | |
|  | | | | |
| **4.** | Please provide a traceability matrix linking the contraindications, warnings and precautions from Risk Management File to the Instructions For Use and CER | | | | |
|  | | | | |
| **5.** | 1. Please indicate where in the risk management file the overall residual risk conclusion is located | | | | |
|  | | | | |

| Section 9: 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)** | | | | | | | | | | | |
|  | Device sub-family | | | Cat. Number | Sterilization Method | Sterilization Location | Protocol/ Report No. | | | | Site resp for Release | |
|  | | |  |  |  |  | | | |  | |
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|  | | |  |  |  |  | | | |  | |
| 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 10: Performance evaluation | | |
| --- | --- | --- |
| 1. | Please provide the necessary performance evaluation report to support the safe use of the device. These data should arise from studies in a clinical or other appropriate environment or result from relevant biological references. | |
| 2. | Performance Data including claims should be supported by a reference measurement system and should contain information on | Yes  No |
| Reference Methods used | Yes  No |
| Reference Materials used | Yes  No |
| The known Reference values | Yes  No |
| Accuracy and measurements | Yes  No |