

**Medical Devices**

Re-Certification Application Form

**Submission Details**

**Please tick all that apply:**

|  |  |  |  |
| --- | --- | --- | --- |
| [ ]  | IVD Annex II List A  | [ ]  | IVDR Annex VIIISelf-Test/Near patient Class D  |
| [ ]  | IVD Annex II List B | [ ]  | IVDR Annex VIIISelf-Test/Near patient Class C |
| [ ]  | IVD Self-Test | [ ]  | IVDR Annex VIII Self-Test/Near patient Class B |
| [ ]  | Fast Track (expedited) | [ ]  | IVDR Annex VIII Companion Diagnostic Class D |
| [ ]  | IVDR Annex VIII Class D  | [ ]  | IVDR Annex VIII Companion Diagnostic Class C |
| [ ]  | IVDR Annex VIII Class C | [ ]  | IVDR Annex VIII Companion Diagnostic Class B |
| [ ]  | IVDR Annex VIII Class B |  |  |
| [ ]  | IVDR Annex VIII Class A sterile  |  |  |
| **Directive/Regulation(s) that apply:** | **NSAI File Number** |
| [ ]  IVD 98/79/EC  | 304.     /      |
| [ ]  | IVDR 2017/746 |  |

|  |  |
| --- | --- |
| 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/ Regulation 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: | Click here to enter text. | Date: | Click here to enter text. |
| Name (please print): | Click here to enter text. |
| Position / Title: | Click here to enter text. |
| Contact person(if different to Manufacturer): | Click here to enter text. |
| e-mail: | Click here to enter text. | Phone: | Click here to enter text. |

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| INSTRUCTIONS |
| 1. Please review current revision of regulations and relevant guidance documentation for completion of application including relevant Directives/Regulations, MEDDEV, NBOG and Standards relevant for medical devices under IVDR (<https://ec.europa.eu/growth/sectors/medical-devices/guidance>) and Annex VIII for Classification of devices under IVDR.
2. Please complete all relevant sections of the form (excluding the NSAI Review sections).
3. Please present the technical documentation in a clear, organised and searchable and unambiguous manner.
4. 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.
5. Please submit an unsigned version of this Application in Word as well as a signed copy - either scanned/secured (pdf) copy.
6. All application forms and supporting data to be forwarded in soft copy via 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** | **IVD**  | **IVDR**  |
| Completed application form (Word format, .doc or .docx)  |[ ] [ ]
| Application (min. Signed Declaration page(s)) scanned (pdf) |[ ] [ ]
| QMS certificates for all sites listed in the application form  |[ ] [ ]
| Declaration of Conformity |[ ] [ ]
| Current revision of Labelling & IFU  |[ ] [ ]
| Vigilance Reports  |  |[ ]
| Marketing Data |  |[ ]
| Essential Requirements Checklist / Safety and Performance Requirements under IVDR |[ ] [ ]
| Harmonised Standards applicable and supporting documentation |[ ] [ ]
| Common Specifications and supporting documentation if necessary |  |[ ]
| Performance/Complaint Analysis  |[ ] [ ]
| Post-Market Surveillance Plan and Report |[ ] [ ]
| UDI labelling and identification current  |[ ] [ ]
| Safety Statement Report |  |[ ]
| Risk Management File including documentation concluding the device is safe for its intended use with supporting documentation for risk ratings |[ ] [ ]
| Sterilisation Validation(s) – if sterile/intended to be sterilised |[ ] [ ]
| Device stability data  |[ ] [ ]
| Electrical Safety Testing data – if necessary |[ ] [ ]
| Software/firmware lifecycle documents – if necessary |[ ] [ ]
| Completed Software Checklist per EN 62304 – if necessary |[ ] [ ]
| Cybersecurity risk assessment and mitigation documents - if necessary |[ ] [ ]
| Data Protection risk assessment and controls - if necessary |[ ] [ ]
| Usability Engineering Plan & Report – if necessary  |  |[ ]
| Bench Testing data – if necessary |[ ] [ ]
| Performance Evaluation Plan and Report(s)  |[ ] [ ]
| Clinical development plan and reports  |[ ] [ ]
| Training manual for end user if applicable |[ ] [ ]
| Periodic Safety Update Report (PSUR) for upload to Eudamed  |  |[ ]
| literature search Protocol and Report (i.e. State of the Art) |[ ] [ ]
| Post Market performance Follow-up (PMPF) Plan and Report  |[ ] [ ]
| Equivalence Claim if applicable  |[ ] [ ]

| 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.As per IVDR 2017/746 a Manufacturer means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trade mark. |

| **Manufacturers Information & Summary Product Data** |
| --- |
| Legal Manufacturer’s Name  | Click here to enter text. |
| Legal Manufacturer’s Address | Click here to enter text. |
| Design Site (s)  | Click here to enter text. |
| Manufacturing Site(s):(i.e. sites of actual manufacture) | Click here to enter text. |
| Assembly Site(s) if applicable.: | Click here to enter text. Click here to enter text. |
| Sterilization Site(s) if applicable.: | Click here to enter text.  |
| Scope of Site(s):(i.e. as shown on the QMS cert) | Click here to enter text. |
| Name and address of EU Authorized Representative(if applicable) | Click here to enter text. |
| Name of Quality/Regulatory Responsible Person | Click here to enter text. |
| Product/Product Family Name:(In compliance with NB/MED/2.5.1/REC4 & NBOG’S Best Practice Guide 2006-2) | Click here to enter text. |
| GMDN Reference Number: | Click here to enter text. | See [www.gmdnagency.com](http://www.gmdnagency.com) |
| UDI Carrier  | Click here to enter text. | IVDR 2017/746 Only  |
| SRN Number | Click here to enter text. | IVDR 2017/746 Only |
| [ ]  | Declaration of Conformity included - Location within submission:  |  |
| Type of IVD as per 98/79 EC  | [ ]  | Annex II List A | [ ]  | Annex II List B | [ ]  | Self Test IVDs not covered by Annex II |
| Type of IVD as per 2017/746  | [ ]  | Annex VIII Class D | [ ]  | Annex VIII Class C | [ ]  | Annex VIII Class B |
| [ ]  | Annex VIII Class A Sterile | [ ]  | Annex VIII Class D Self-Test/near test | [ ]  | Annex VIII Class C Self-Test/near test |
| [ ]  | Annex VIII Class B Self-Test/near test | [ ]  | Annex VIII Class D Companion Diagnostic | [ ]  | Annex VIII Class C Companion Diagnostic  |
| [ ]  | Annex VIII Class B Companion Diagnostic |  |
| Chosen Conformity Assessment Route | Click here to enter text. |
| Rationale | Click here to enter text. |
| Date of this application(i.e. date of Declaration of Applicant): | Click here to enter text. |
| 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 1), please make sure that the WORD version is supplied.  |
| Table 1: Product Family Information |
| Sub-Family | Model/Catalogue Number | Description | Class | UDI  |
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| SECTION 2: DESCRIPTION OF DEVICE and intended use  |
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| Please provide a full description of the device which demonstrates that the product is covered under Directive 98/79/EC or regulation 2017/746: |
| 1. | Description of the device and intended purpose which may include information on * what is to be detected
* its function -screening , monitoring etc.,
* specific disorder, condition or risk factor
* is the device automated
* qualitative or quantitative
* type of specimen is required
* testing population
 |
| 2.  | Please Provide the most recent version of IFU and product labelling for reviewClick here to enter text. |
| 3. | Please enter a full description of the intended use of the device, which supports the product classification:Click here to enter text. |
| 4. | Has there been any change to the intended use since the previous submission Click here to enter text. |
| 4. | List of any contra-indicationsClick here to enter text. |
| 5. | List of any precautions/warnings Click here to enter text. |
| 6. | List any Changes to Labelling since the previous 3 year review and provide the amendment number submitted to NSAI.Click here to enter text. |

| SECTION 3: Substantial ChangesPlease Provide a complete listing of all substantial changes made during the current product certification cycle  |
| --- |
| 1. | Products affected and amendment: |
| Click here to enter text. |
| 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 4: 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) |
| Click here to enter text. |
| 3 | Please define the in-use stability if applicable |
| Click here to enter text. |
| 4 | Please define the re-constitution stability if applicable  |
| Click here to enter text. |
| 5 | Please define the Open Vial/Bottle stability if applicable |
| Click here to enter text. |
| 6 | Please define the Shipping/ Transport stability including duration of transport and expected transport temperatures and humidity.  |
| Click here to enter text. |
| 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:  |
| Click here to enter text. |
| 8 | Is regular monitoring of the stability of the IVD reagent already on the market completed[ ]  Yes [ ]  No |
| If Yes-Provide data and summary Click here to enter text. |
| If no -Please provide Rationale Click here to enter text. |

| Section 5: 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 2 below and
 |
| 1. Provide evidence of compliance to the new standard, addressing how the revised standard has been considered and implemented.
 |
| **For current list of harmonised standards**<https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/iv-diagnostic-medical-devices_en> |
| **Table 2: Harmonised standards** |
| **Harmonised Standard** | **Year** | **Compliance Yes/No** | **Evidence of compliance** |
|  |  |  |  |
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| Section 6: 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.** | **VIGILANCE 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 |
|  **Table 3: Vigilance Summary** |
| **Unique ID No:** | **Competent Authority** | **Details of Investigation** | **Root Cause** | **CAPA Raised - Y/N & Details** | **Status** |
|  |  |  |  |  |  |
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| Section 7: Risk Management |
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| 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 |
| Click here to enter text. |
| **3.** | Please provide the document number of the Risk Analysis Matrix / Risk assessment summary matrix/documents and location within the technical file supplied -  |
| Click here to enter text. |
| **4.** | Please provide a traceability matrix linking the contraindications, warnings and precautions from Risk Management File to the Instructions For Use and CER |
| Click here to enter text. |
| **5.** | 1. Please indicate where in the risk management file the overall residual risk conclusion is located
 |
| Click here to enter text. |

| Section 8: Sterilisation |
| --- |
| 1.  | Is product provided Sterile [ ]  YES [ ]  NO  If no, please continue to section 10 |
| 2. | If the product is placed on the market in a sterile condition please provide the sterilization method used Click here to enter text. |
| 3. | Please provide the necessary sterilization validation protocol(s) & report(s) about packaging, sterilization and maintenance of sterility and populate the table below. The report should address bioburden, pyrogen and if applicable sterilant residues testing.  |
| [ ]  | Initial validation information: Year Click here to enter text. |
| [ ]  | Latest revalidation (if initial validation >1yr) |
| **Table 4. Sterilisation Information Summary** |
| **Device****sub-family** | **Cat.****Number** | **Sterilisation Method** | **Sterilisation Location** | **Protocol / Report No** | **Site Resp for Release** |
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| Section 9: Electrical / ELECTRONIC IVD Equipment, IVD Equipment with software/firmware, and IVD Standalone software |
| --- |
| **Definition: NSAI refers the manufacturer to the equipment definitions in EN 61010-1: 3.1.1 FIXED 3.1.4 HAND-HELD****3.1.2 PERMANENTLY CONNECTED 3.1.5 TOOL****3.1.3 PORTABLE 3.1.6 DIRECT PLUG-IN****E** |
| 1.  | Does the IVD Product conform to one of the definitions above:  | Conforms to one of definitions- Yes [ ]  No [ ]  | If conforms, enter equipment definition       |
| 2. | Have the Applicable requirements of EN 61010-2-101 including the mandatory risk assessment to EN ISO 14971 been applied to the IVD Equipment  | Yes [ ]  No [ ]  |
| 3. | What is the expected Service Life of the IVD Equipment  | Years Click here to enter text. |
| 4a. | Do any other additional standards (e.g. IVD for self-test, IVD for pro use only) apply  | Yes [ ]  No [ ]  |
| 4b. | If Yes please provide detail of standards |       |
| 5. | In respect of the IVD Equipment please provide each of the following as applicable and detail the location within the submission:  |
| Test Report to EN 61010-2-101 (this will generally include report to EN 61010-1) | Yes [ ]  No [ ]        |
| The associated Risk Management File | Yes [ ]  No [ ]        |
| Labelling and Marking (e.g. EN 18113-3 or EN 18113-5) | Yes [ ]  No [ ]        |
| EMC. (e.g. EN 61326-2-6) (note: if the IVD product is electrically operated, this standard is generally applicable) | Yes [ ]  No [ ]        |
| The EN 62304 Software Development Process, Risk Management, and Validation Documentation (see 6e) | Yes [ ]  No [ ]        |
| 6a | Does the IVD Equipment incorporate Software/Firmware | Yes [ ]  No [ ]  |
| 6b | If Yes, please indicate all software/firmware in the IVD Product/submission (please be sure to answer 6f below) | [ ]  Instrument [ ]  Computer[ ]  Mobile/Tablet [ ]  Cloud  |
| 6c | If Yes -Have the requirements of EN 62304, including the mandatory risk assessment to EN ISO 14971, been applied to Software/Firmware for each of the software items checked in 4b? | Yes [ ]  No [ ]  |
| 6d | Please provide/submit the EN 62304 safety classification (A, B, C) and rationale for each software or firmware item checked in 6b. |
| 6e | Please also provide all documentation to demonstrate compliance with EN 62304: as shown below. If you would like a EN 62304 Document Checklist Form, pls request this of your File Manager. |
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| **Table 5: 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 |

 |
| 6f | Does the IVD Product incorporate Standalone Software (also referred to as SaMD (Software as a Medical Device) or COTS (Commercial Off the Shelf Software?) Yes [ ]  No [ ]   |
| 6g | If “Yes” have Cybersecurity requirements been addressed (e.g. FDA Premarket Guidance on Cybersecurity)? If yes, please provide and detail the location within the submission. If no, detail the rationale why Cybersecurity requirements are not applicable.Yes [ ]  No [ ]        |

| SECTION 10: PERFORMANCE EVALUATION AND POST MARKET PERFORMANCE FOLLOW UP (PMPF) |
| --- |
| Information required for IVDD 98/79 EEC only in section 1 to 3.  |
| 1. | Please provide the necessary updated performance evaluation report since the last submission 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. m relevant This should include the following:   |
|  | Has this been updated since the previous submission? If Yes -Provide all updates If No -Justify       |
| 2. | Is the performance evaluation conducted to EN 13612 | Yes [ ]  No [ ]        |
| 3. | 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 [ ]        |
| Information required for IVDR 2017/746 Annex XIII only in section 4-10 |
| 4. | Please provide the location of the updated performance report which is to include an updated Scientific Validity Report, Analytical Performance report and a Clinical Performance report as detailed in chapter VI, Article 56**Performance evaluation should be updated during the lifecycle of the device.** **Class C and D are to be updated when necessary but at  *least* annually**  | Click here to enter text. |
| 9. | **Class A and B** Please provide the location of the Post Market Surveillance ReportIncluding analysis of data gathered since the previous submission and corrective actions derived.  | Click here to enter text. |
| 10. | **Class C and D** Please provide the location of the annual Periodic Safety Update Report (PSUR) Including* analysis of data gathered since the previous submission and corrective actions derived.
* The conclusion of the risk benefit risk determination
* The main findings of the PMPF
* The volume of sales, estimate of the size and other characteristics of the end users
 | Click here to enter text. |
| 11. | If required Please provide the “equivalence claim report” where the clinical evidence is based on data, in total or in part, from devices which are claimed to be similar or equivalent to the device under assessment.  | Click here to enter text. |