

**Medical Devices**

# New Application Form

* **IVD Annex II List B**
* **IVD Self-Test**

[**Submission**](#aaNSAI_TableOfContents) **Details**

**Please tick all that apply:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
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|  | IVD Annex II List B | | |  |
|  | IVD Self-Test | | |  |
|  | Transfer (from another NB) | | | |  | | --- | |  | |
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|  | | | | | |
| PO Number | |  | | | |
|  | | | | | |
| **Directive(s) that apply:** | | | **NSAI File Number** | | |
|  | IVD 98/79/EC | | 304.     / | | |

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

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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 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 all sites in Table 1 |
|  | (Draft) Declaration of Conformity |
|  | (Draft) Labelling & IFU |
|  | Essential Requirements Checklist |
|  | Performance/Complaint Analysis |
|  | Risk Management documentation |
|  | Sterilisation Validation(s) – if provided sterile |
|  | Packaging and device stability data – if necessary |
|  | Design Verification and Validation documentation -if necessary |
|  | Performance Evaluation Report to support product claims |
| **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)*** | |

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| --- | --- | --- | --- | --- | --- |
| 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 inform NSAI which issued the EC design-examination certificate of any changes to the approved design, wherever the changes could affect 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 and supply it with all relevant information, in particular:   - 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.   * On receipt of the CE Mark approval from NSAI, it is our intention to commercialise the product. In the event of non-commercialise of the said product we commit to notify NSAI of this decision. * 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: | |
| Vigilance Contact person  (if different to above) | |  | | | |
| e-mail | |  | Phone: | | |  |

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| 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. |

| **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): | | | | | | Class | | | | |
| 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. | | | | | | | | | | |

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| --- | --- | --- | --- |
| 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 Directive 98/79/EC: |
| 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 TRANSFER  Please refer to applications checklist | | | | | |
| 4. | If you are not the maker of the device does this identical product carry CE marking by the maker | |  | Yes |  | No |
| If “Yes” – Please supply a copy of the contract between your company (Own Brand Labeler-OBL) and the actual maker (Original Equipment Manufacturer-OEM) Detailing responsibilities for:   1. Design Changes.      1. Vigilance Issues and complaint Handling.      1. Changes to the OEM Quality Management system and communications about such changes.      1. Changes to the OEM manufacturing environment and communications about such changes. | | | | | |

| 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. | Are symbols being utilized in product labeling or IFU’s . | | | |  | Yes |  | No |
| If yes are symbols in compliance with– | | | | | | | |
| EN 1041: |  | | EN ISO 980: |  | | | |
| If compliance with these vertical labelling standards is not claimed, please justify - | | | | | | | |
|  | | | | | | | |
| 44 | Do any of the following labelling requirements apply?  EN 61010-2-101 Yes -  No  N/A  EN 61326-2-6: Yes -  No  N/A  EN 13532:2002 Yes -  No  N/A  EN ISO 15197:2015 Yes -  No  N/A | | | | | | | |
| 5. | If an IFU is not provided please rationalize how the device can be used safely in the absence of such instructions | | | | | | | |
|  | | | | | | | |

| Section 6: Solutions to Essential Requirementsand Harmonised Standards | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 1. | Location of the solutions to Essential Requirements (ER) in the supporting documentation: | | | | | | |
|  |
| 2. | Please indicate how relevant essential Requirements Annex 1 of the Directive are met | | | | | | |
| 3. | Are Harmonised Standards being used | | |  | Yes |  | No |
| If “No” please justify - | | | | | | |
| 4. | 1. Please list the relevant Harmonised standards related to the IVDD in the table below | | | | | | |
| 1. **Applicable Harmonised Standards List** | | | | | | |
| 1. Standard | 1. Year | 1. 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. Clearly catergorize the complaints e.g. Justified/Non Justified complaints, Device Performance Related, Clinical User Related, Labelling Issue Etc. | | | | | | | | | | |
| 4. | Please summarize all global Vigilance issues that fulfil the European Reporting requirements in the following/similar format: | | | | | | | | | | | |
| Report Number | | Competent Authority | Details of Investigation | Root Cause | | CAPA Raised Y/N Details | | | | Status | |
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| Section 8: 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.  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 | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 9.1 Sterilisation Validation | | | | | | | |
| **1.** | Is product provided Sterile  YES  NO    If no, please continue to section 10 | | | | | | |
| **2.** | Please provide the necessary sterilization validation protocol(s) & report(s) and populate the table below | | | | | | |
|  | Initial validation information: Year | | | | | |
|  | Latest revalidation (if initial validation >1yr) | | | | | |
| **Sterilisation Information Summary** | | | | | | |
| **Device**  **sub-family** | | **Cat.**  **Number** | **Sterilisation Method** | **Sterilisation Location** | **Protocol / Report No** | **Site Resp for Release** |
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| Section 10: Stability | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Does the product have a shelf life | | | |  | | Yes |  | No | |
| If “no” please justify: | |  | | | | | | | |
| 1. | Please define the shelf life/expiry date | | | | Years | | | |
| 2. | Please provide details and evidence of other stability claims e.g. On board Stability, Open Vial, Transport | | | |  | | | |
| 3. | Please describe the preconditioning applied (eg. Ageing, transport etc): | | | | | | | |
|  |  | | | | | | | |
| 4. | Is compliance with EN ISO 23640 latest version claimed | | |  | | Yes |  | No |
| If “no” please justify: |  | | | | | | |
| 5. | Confirm start date of real time Packaging studies | |  | | | | | |
| 6. | Please list all relevant reports which substantiate Packaging shelf life – | | | | | | | |
|  | | | | | | | |

| Section 11: Medical Electrical Equipment (ME EQUIPMENT)& mEDICAL eLECTRICAL sYSTEMS (me sYSTEMS) | | | | |
| --- | --- | --- | --- | --- |
| **Definition:**  **ME electrical equipment** -having an applied part or transferring energy to or form the PATEINT or detecting such energy transfer to or from the patient and which is:   * + 1. provided with not more than one connection to a particular supply mains; and     2. intended by its manufacturer to be used:        1. in the diagnosis, treatment, or monitoring of a patient; or        2. for compensation or alleviation of disease, injury or disability   **ME System** – combination, as specified by its manufacturer, of items of equipment, at least one of which is ME Equipment to be inter-connected by functional connection or by us of a multiple socket-outlet | | | | |
| 1. | Is the Medical Device Product: | ME Equipment- Yes  No | | ME system- Yes  No |
| 2. | Have the Applicable requirements of EN 61010-2-101 including the mandatory risk assessment to EN ISO 14971 been applied to the IVD ME Equipment/ME System | | | Yes  No |
| 3. | What is the expected Service Life of the ME Equipment/ME System | | | Years |
| 4. | What is the Essential Performance of the ME Equipment/ME System | | |  |
| 5. | Does the ME Equipment/ME System incorporate Software | | | Yes  No |
| 6. | If Yes -Have the requirements if EN 62304, including the mandatory risk assessment to EN ISO 14971, been applied to Software development | | | Yes  No |
| 7. | Do any other additional standards apply | | | Yes  No |
| 8. | If Yes please provide detail of standards | | |  |
| 9. | In respect of the ME Equipment/ME system please provide each of the following as applicable and detail the location within the submission: | | | |
| Test Report to EN 61010-2-101 | | | Yes  No |
| The associated Risk Management File | | | Yes  No |
| The EN62304 Software Development Process and Validation Report as we as the software Risk Assessment | | | Yes  No |
| Labelling and Marking | | | Yes  No |
| Any other reports e.g. EN 60132-2-6 | | | Yes  No |
| 10 | Please provide the safety classification (A, B, C) and rationale for each software or firmware unit. | | | |
| 11 | Please also provide all documentation to demonstrate compliance with EN 62304: as shown below | | | |
| 12 | |  |  |  |  | | --- | --- | --- | --- | | **Table: 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 Software  requirements | X | X  (incl. RISK CONTROL measures) | X  (incl. RISK CONTROL measures) | | 5.3 Software  ARCHITECTURAL design | N/A | X | X  (incl. segregation for RISK CONTROL) | | 5.4 Software detailed  design | N/A | X | X  (incl. detailed design of SOFTWARE UNIT & interfaces) | | 5.5 SOFTWARE UNIT  implementation | X | X  (incl. verification & acceptance criteria) | X  (incl. verification & acceptance criteria) | | 5.6 Software integration  & integration testing | N/A | X | X | | 5.7 SOFTWARE SYSTEM  testing | 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 Software  maintenance plan | X | X | X | | 6.2 Problem &  modification analysis | X | X  (incl. analysis of CHANGE REQUESTS) | X  (incl. analysis of CHANGE REQUESTS) | | 6.3 Modification  implementation | X | X | X | | 7.1 Analysis of software  contributing to hazardous  situations | N/A | X | X | | 7.2 RISK CONTROL  measures | 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 configuration  Management PROCESS | X | X | X | | 9 Software problem  resolution PROCESS | X | X | X | | | | |
|  | 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: design dossier-design vERIFICATION AND vALIDATION(aNNEX III SECTION 6: DEVICES FOR SELF TESTING | | | |
| --- | --- | --- | --- |
| 1. | Is the device | Self Testing Yes  No | |
| 2. | Provide the necessary design documents to demonstrate the following: | | |
| Data to demonstrate that output meet inputs-results obtained from Laboratory testing and conclusions made are applicable to the design specifications and performances claimed | | Yes  No |
| Design Validation data to include a critical analysis or relevant scientific literature | | Yes  No |
| Historical Evidence that similar designs and/or materials are clinically safe an | | Yes  No |
| Clinical investigation or trial to demonstrate that the product is capable of meeting the requirements for its intended use | | Yes  No |
| 3. | Provide the necessary design documents to demonstrate the following for Devices for Self-testing: | | |
| Data to prove device is easy to use by the intended lay user and all stages of the procedure | | Yes  No |
| The reduction of risk of user error in the handling of the device and the interpretation of the results | | Yes  No |

| Section 13: 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. m relevant This should include the following: | |
| 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 |