

**Medical Devices**

# Significant Change Application Form

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

**Please tick all that apply:**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Significant Change Review | | | | | | | | |
|  | | | | | | | | | |
| PO Number | | |  | | | | | | |
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| **Directive(s) that apply:** | | | | | | | **NSAI File Number** | | |
|  | IVD Annex II List B | | | | | | 304.     / | | |
|  | IVD Self-Test | | | | | |  | | |
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|  |  | | | | | |  | | |
| If OBLs apply to this product, please state the relevant product families below: | | | | | | | | | |
|  | / | | | ; | / | ; | | / |  |

|  |  |
| --- | --- |
| 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 |
|  | Performance/Complaint Analysis |
|  | Risk Management documentation |
|  | Sterilisation Validation(s) – if sterile/intended to be sterilised |
|  | Packaging and device stability data – if necessary |
|  | Electrical Safety Testing data – if necessary |
|  | Validation and verification reports if required |
|  | Software/firmware lifecycle documents – if necessary |
| ***(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 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** | | | | | | |
| Signed  on 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 | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 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. | | | | | | | | |

| 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 the table), please make sure that the WORD version is supplied. | | | |
| --- | --- | --- | --- |
| Product Family Information | | | |
| **Sub-Family** | **Model/Catalogue Number** | **Description** | **Class** |
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| Section 2: NATURE OF THE CHANGE | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| 1. | Please provide a clear, detailed description of the change(s): | | | | | |
|  |  | | | | | |
| 2. | Did the change(s) arise from a vigilance or performance issue | |  | Yes |  | No |
|  | If “Yes” – please advice | | | | | |
|  | | | | | |
| 3. | Has NSAI received 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 Competent Authority report(s) along with the completed NSAI Vigilance Form located at [<http://www.nsaiinc.com/services/MedicalDevice> -“Vigilance Reporting”] to [vigilance@nsai.ie](mailto:vigilance@nsai.ie) | | | | |
| 4. | 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 with supporting documentation. | | | | | |
|  |  | | | | | |
| 5 | For those failure modes associated with the identified Root Causes, please clarify if the Occurrence Rates outlined in the Risk Management File required an update based on the observed real world rates. | | | | | |
|  |  | | | | | |

| SECTION 3: INTENDED USE OF THE DEVICE |
| --- |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1. | Is there a change in Intended Use |  | Yes |  | No |
| 2. | Please enter a full description of the revised intended use and/ or indications for use of the device- | | | | |
|  | | | | |
| 3. | Does this change impact the classification/rule |  | Yes |  | No |
| If “No” please justify - | | | | |
|  | | | | |

| Section 4: Labelling and IFU | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 1. | Is there a change to the Labelling/IFU | | |  | Yes |  | No |
| If yes | | | | | | |
| Please supply a sample of the revised draft labelling & IFU in English. | | | | | | |
| 2. | Location of the sample Label(s) & IFU in the supporting documentation |  | | | | | |
| 3. | Are copies of all labelling provided? | | |  | Yes |  | No |
| If No please rationalize that the sample provided is representative of the family | | | | | | |
|  | | | | | | |
| 4. | Please clarify the exact nature of change(s) to the labelling/IFU based on the proposed change(s) under review – | | | | | | |
|  | | | | | | |
| 5. | Are the requirements of EN ISO 980 & EN 1041 being met | | |  | Yes |  | No |
| Version of Standard – | |  | | | | |
| If compliance with these vertical labelling standards is not claimed, please justify - | | | | | | |
|  | | | | | | |
| 6. | 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 | | | | | | |

| Section 5: Solutions to Essential Requirementsand Harmonised Standards | | | |
| --- | --- | --- | --- |
| 1. | Please indicate how relevant Essential Requirements (Annex I) of the Directive are met for the proposed changes. | | |
|  |
| 2. | Location of the revised solutions to Essential Requirements in the supporting documentation | | |
| 3. | 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 6: Risk Management | | | | | |
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| Please provide a Risk Analysis/ Risk Management report/document/file, including a signed and dated conclusion regarding residual/remaining risks. The analysis and conclusion shall include clear reference to the proposed change(s) | | | | | |
| If applicable, please indicate which of the multi-functional team provided the clinical input – i.e. risks associated with the clinical use of the device. | | | | | |
| 1. | Did the proposed change affect or change any existing risks |  | Yes |  | No |
|  | If “No” please justify - | | | | |
|  | | | | |
| 2. | Did the proposed change introduce any new risks |  | Yes |  | No |
|  | If “No” please justify - | | | | |
|  | | | | |
| 3. | Was the Risk review documented  *(e.g. during change control process, update to FMEA, Memo to file etc.)* |  | Yes |  | No |
|  | If “No” please justify - | | | | |
|  | | | | |
| 4. | If no update to Risk Management File, please provide rationale: | | | | |
|  | | | | |

| Section 7: Stability | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Does the change affect the products shelf life | | | | |  | | Yes |  | No |
| If “no” please justify: | |  | | | | | | | |
| 1. | Please define the shelf life/expiry date | | | | | Years | | | |
| 2. | Is the aging based on | |  | Accelerated |  | Real Time data | | | |
| 3. | Is compliance with EN ISO 23640 latest version claimed | | | |  | | Yes |  | No |
| If “no” please justify: |  | | | | | | | |
| 4. | Confirm start date of real time studies | | | |  | | | | |
| 5. | Please list and provide all relevant stability reports to justify the proposed change | | | | | | | | |
| Protocol # |  | | | | | | | |
| Number # |  | | | | | | | |

| Section 8: Sterilisation | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **1.** | Does the proposed change affect sterilisation  YES  No  If Yes, Please complete the form below | | | | | | |
| **2.** | Please provide the necessary sterilization validation protocol(s) & report(s) and populate the table below for the change | | | | | | |
| **Sterilisation Information Summary** | | | | | | |
| **Device**  **sub-family** | **Cat.**  **Number** | **Sterilisation Method** | **Sterilisation Location** | **Protocol / Report No** | | **Site Resp for Release** |
|  |  |  |  |  | |  |
|  |  |  |  |  | |  |
|  |  |  |  |  | |  |
|  |  |  |  |  | |  |
| 3. | Is compliance with the following standards claimed | | | | | | |
| EN ISO 11135-1 (EtO) | | | Yes | | No | |
| EN ISO 11137-1, | | | Yes | | No | |
| EN ISO 11137-2 (Irradiation) | | | Yes | | No | |
| EN ISO 13408 (Aseptic Processing) | | | Yes | | No | |
| EN ISO 17665-1 (Moist Heat) | | | Yes | | No | |
| If no, Justify | | |  | | | |

| Section 9: Medical Electrical Equipment (ME EQUIPMENT)& mEDICAL eLECTRICAL sYSTEMS (me sYSTEMS) | | | | |
| --- | --- | --- | --- | --- |
| Does the change affect the Medical Electrical Equipment/Medical Electrical Systems  Yes  No  If Yes, Please complete the form below. | | | | |
| 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 s 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 61010-2-101:2002 | | | 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 10: design dossier-design vERIFICATION AND vALIDATION(aNNEX III SECTION 6: DEVICES FOR SELF TESTING) | | |
| --- | --- | --- |
| 2. | Provide the necessary design documents for the proposed change to demonstrate compliance | |
| 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 | 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 11: Performance evaluation | | |
| --- | --- | --- |
| 1. | Please provide the necessary performance evaluation report to support the safe use of the device following this change. These data should arise from studies in a clinical or other appropriate environment or result from relevant biological references. This should include the following: | |
| 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 |