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:

☐ MDD (93/42/EEC)
☐ AIMD (90/385/EEC)
☐ TSE (2012/722/EU)
☐ Class 1S&M
☐ Class 2A &2B non-implantable
☐ Class 2B implantable, Class 3, AIMD

NSAI File Number

252. /
253. /

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

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/

5. Supporting documents should be in SEARCHABLE format

6. Applications and supporting documentation must be in English

7. 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
	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
☐ 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

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:

   (a) List any updated Harmonized Standards in Table 3 below and

   (b) 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	Compliance Yes/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	Compliance Yes/No	Evidence of Compliance (e.g. Delta or new report)

SECTION 4: PERFORMANCE / COMPLAINT ANALYSIS

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

SECTION 4: PERFORMANCE / COMPLAINT ANALYSIS

Please provide a summary analysis of product complaints and Vigilance Reportable Incidents as outlined below

	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

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

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.			

SECTION 6 – CLINICAL PERFORMANCE (HUMAN)

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

Please use this section to document any additional information not already covered.

Please complete Table 6.

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		