Client Communication regarding NSAI Notified Body Designation to Medical Devices Regulation (MDR) 2017/745

Dear Valued Clients,

NSAI are proud to announce that we have achieved designation under Medical Device Regulation 2017/745. We are 11th notified body to be designated under the new regulation which was published on the 5 May 2017 and manufacturers will need to comply with from the 26th May 2020

NSAI is now able to provide conformity assessments under the MDR to the scope documented on the NANDO database. The applied for scope mirrors our current client portfolio.

The designation scope includes:

- Active implantable devices
- Active non-implantable devices for imaging, monitoring and/or diagnosis
- Active non-implantable therapeutic devices and general active non-implantable devices
- Non-active implants and long term surgically invasive devices
- Non-active non-implantable devices

The scope of NSAI's designation also covers new categories of devices with specific characteristics that were introduced under MDR such as:

- Reusable surgical instruments
- Devices locally dispersed in the human body or intended to undergo a chemical change in the body
- Devices without an intended medical purpose as per Annex XVI of the Regulation (conditional on Common Specifications being published)

NSAI will be performing conformity assessment activities under Annex IX Chapter I and II and Annex XI Part A.

For clients wishing to engage under the MDR immediately NSAI will be accepting applications regarding the scheduling of your conformity assessment activities from April 1st 2020.

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NSAI MDR Application Process

A company's decision to transition to MDR is dependent on a number of factors: (the following is not an exhaustive list)

- New product introduction(s)
- Expiry date of existing AIMD/ MDD certificates
- Certain significant changes to products certified under the AIMD/MDD
- Classification of device

NSAI is happy to discuss the timing of your transition.

All incoming applications under the MDR will be required to contract under the MDR 2017/745 and complete a request for quote (RFQ)/application form when ready to transition to MDR. NSAI have made our fees publicly available on our website as required; however, a more detailed breakdown will be provided during the RFQ/application process.

NSAI Process for MDR application and certification

- Complete an RFQ/application
- Accept quotation/ contract
- Schedule Product/Technical documentation Review and QMS audit activity
- Technical documentation review and QMS audit activity will happen simultaneously
- Certification under MDR achieved and surveillance cycle begins

All forms will be available on the 01st April from www.nsai.ie.

Please contact medical.devices@nsai.ie for further information.

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NSAI Fees for Conformity Assessment Activities (EUR)

Medical Devices Regulation (MDR and IVDR)

Effective Feb 2020 for MDR/IVDR applications only -For External Use

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Conformity assessment Activities and their Fees

Product File Submission Completeness Check*	**€1,500**
Annual Product License*	**€2,500**

Quality System Audit Fees Per Day:

Medical Device MDR/IVDR QMS Audit **	**€2,200**

Unannounced Audit Fees Per Day:

NSAI is required to perform routine unannounced audits of manufacturers and/or their critical sub-contractors or crucial suppliers. Duration of unannounced audits is at least one day and performed by two auditors, at least once during the 5-year certification cycle with some exceptions.

Medical Device MDR/IVDR Unannounced Audit **	**€4,400**
Medical Device MDR/IVDR Unannounced Audit **	**€4,400**

Technical Documentation Review Fees

The review of technical documentation requires the highest levels of technical expertise. The time spent on these reviews is dependent on a number of critical factors:

- Quality and completeness of the submission
- Class of the device
- Whether the device is novel and/or high risk

Regulation (MDR/IVDR) Technical Documentation Review*	**€3,000**

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Fees may vary slightly due to currencies and different travel policies that may apply to some specific geographies.

A more comprehensive breakdown of Fees is available following the RFQ/Application process

*This fee applies to each individual product file submission

**Fees associated with travel time, expenses and other schemes are dependent on contract and geography

***This fee applies to initial conformity assessments, significant change reviews, recertification reviews, post market surveillance and vigilance activities.

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