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Low rate of Notified Body designations under MDR and IVDR causes bottleneck concerns for the European MedTech Industry

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Under the new Medical Devices and In-Vitro Devices Regulations, the designation of existing Notified Bodies expires on 26 May 2021. Their re-designation, in line with the requirements of these Regulations, is required to maintain their ability to continue oversight of medical devices and active implantable medical devices. Similarly, the designation of Notified Bodies authorised to assess in vitro diagnostic medical devices will expire on 26 May 2022.

Given that the new Regulations have broadened the scope of medical devices subject to compulsory conformity assessments and the low rate of re-designation of Notified Bodies, the European MedTech Industry is justifiably concerned that a device certification bottleneck will result in a shortage of products on the market.

As the only Irish Notified Body in the MedTech space, the NSAI's approval under the MDR is significant as it ensures continuity of certification for manufacturers who depend on its services. It also upholds Ireland's reputation as being a centre of excellence and a hub for medical technology companies.

The NSAI recently confirmed it is currently progressing its re-designation application under the IVDR with the Commission and the HPRA and hopes to achieve re-designation status by the second quarter of 2021.

MDR - STATUS OF NOTIFIED BODIES

The Medical Devices Regulation (EU) 2017/745 (**MDR**) provides for the up-classification of certain existing devices, with the effect that many devices previously falling outside the ambit of conformity assessments conducted by Notified Bodies are now obliged to be assessed.

A surge in demand for Notified Bodies' services is therefore expected once the MDR becomes fully applicable on 26 May 2021. Although the MDR application date is imminent, many European based medical device manufacturers are uncertain when, and if, their Notified Body will be designated.

As of March 2020, the European Commission (**Commission**) had received 44 MDR Notified Body applications. This represents 86% of existing MDD Notified Bodies.

The Commission publishes the re-designation of Notified Bodies on the NANDO (New Approach Notified and Designated Organisations) website as and when they arise. As of September 2020, there are 16 approved Notified Bodies under the MDR, including the NSAI which was approved by the Health Products Regulatory Authority (**HPRA**).

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Services of Notified Bodies Under the MDR and IVDR

The demand for services of Notified Bodies will increase

The ability to self-assess devices will decrease.

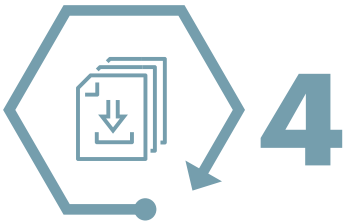
NSAI - MD/IVD APPROVAL PROCESS

The process whereby a Medical Device (**MD**) or an In Vitro Diagnostic Medical Device (**IVD**) manufacturer can apply to the NSAI to conduct a conformity assessment is as follows:

1. The MD/IVD manufacturer completes a Request for Quotation/ Application for NSAI Medical Device Services.

2. Upon receipt of the quotation and the manufacturer's acceptance of the fee, a contract is signed between the parties.

3. A date for the Product and Technical Documentation audits are scheduled so both audits can proceed simultaneously.



4. The NSAI provide three suites of forms to be downloaded depending on the classification of the manufacturer's device in question. This must be completed before the technical review can commence. The forms are accessible via the NSAI website.

5. Information to be provided in the above forms includes but is not limited to issues such as labelling, risk management, sterilisation, clinical review, harmonised standards and common specifications.

6. Following the audits, certification under the MDR may be achieved. Should the MD/IVD manufacturer be dissatisfied with the designated certification, they can appeal the Notified Body's decision to the HPRA.

IVDR - STATUS OF NOTIFIED BODIES

Under the 'old' IVDD regime, merely 10-20% of IVDs are subjected to an assessment by a Notified Body. This is set to increase significantly to 80-90% under the IVDR regime. It is anticipated that this will cause a rise in demand, a likely bottleneck for approvals of IVDs, and is understandably of concern to manufacturers.

As of March 2020, the Commission had received 14 IVDR Notified Body applications which represented 62% of existing Notified Bodies under the IVDD. Since then however, only 4 Notified Bodies have been approved, none of which are based in Ireland.

> The NSAI recently confirmed it is currently progressing its re-designation application under the IVDR with the Commission and the HPRA. Due to delays caused by the COVID-19 pandemic, it is unlikely to obtain approval this year, however the NSAI hopes to achieve re-designation status by the second quarter of 2021.

Although the IVDR is not fully applicable until 26 May 2022, it is crucial that Notified Body approval rates improve significantly to ensure existing devices are kept on the market and new devices reach patients efficiently.

Medical device companies should be aware that they are not restricted to obtaining approval from Notified Bodies in the jurisdiction in which they operate. Conformity assessments can be sought by an approved Notified Body in any Member State provided they are authorised to perform assessments on the specific classification of the device at issue.

UK NOTIFIED BODIES FOLLOWING BREXIT

In the event of a disorderly Brexit, the placing of medical devices on the Great Britain (England, Scotland and Wales), Northern Ireland and European Union markets from January 2021, becomes a frustratingly complex ordeal, with different regulatory regimes applying to all three markets, and different conformity marks applied to devices sold in each market, namely the UKCA Mark, CE or CE UK(NI) Mark and CE Mark respectively. Detailed guidance on the various regimes and how they interact is available on the gov.uk website.

All Notified Bodies in the UK will cease to be recognised after the Brexit transition period ends on 31 December 2020. All products certified by a UK Notified Body must be placed on the EU market before the end of the transition period, if not they will need to be re-certified. From 1 January 2021, CE certificates issued by EEA based Notified Bodies will continue to be valid for the Great Britain market until 30 June 2023.

WHAT SHOULD YOU DO IF YOU CURRENTLY RELY ON A UK NOTIFIED BODY?

- The Commission has recommended that all MD/IVD manufacturers currently relying on a UK Notified Body enquire as to whether it has or plans to set up in an EU-27 Member State.
  - › If it does, then your UK Notified Body may already be taking steps of its own to ensure supply into the EU market is uninterrupted. We advise that you liaise with them to ensure they have begun the process of transferring your CE certificate files to its new EU-27 Member State base.
  - › If your existing UK Notified Body does not intend to set up an EU-27 Member State base, you are required to identify an alternative EU Notified Body from the NANDO website and either arrange for your files to be transferred to them before 1 January 2021 or get your device reassessed.

It is advised that your product certification is transferred to an EU based Notified Body before 31 December 2020. If it is not, you will be faced with the burden of starting the process of certifying your MD/IVD from scratch.

Additionally, we advise manufacturers with a base in both the UK and an EU-27 country, to reorganise their business processes to minimize disruption in the supply chain come January 2021.

GUIDANCE

Although MDs and IVDs continue to be certified and placed on the market under the old system, medical device companies are advised to be proactive in adapting to the requirements of the Regulations to avoid unnecessary approval delays and market shortages.

If you require any further information on Notified Bodies or any other aspect of the MDR or IVDR, please contact Charleen O'Keeffe or Laura Scott.

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