

Notified Bodies (NBs) – A Key Pillar of the Medical Technology Regulatory System

Notified Bodies are responsible for assessing medical devices (MDs) and *in vitro* diagnostics (IVDs). They are an indispensable part of the regulatory system since they grant a CE mark to each device before it can be placed in the EU market.

Notified Bodies are undergoing a significant revamp in order to comply with their greater obligations according to the new Medical Device and In Vitro Diagnostic Regulations.

Key facts about Notified Bodies



Independent



Impartial



Designated and supervised
by National Authorities



Grant EU-wide
product approval

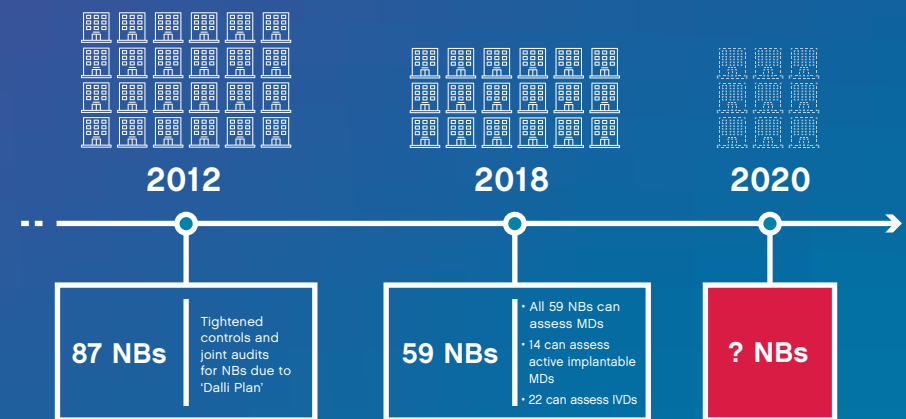


Public or private



Identified by a 4-digit
number, placed with
the CE mark

How many Notified Bodies (re-)certify MDs and IVDs?*

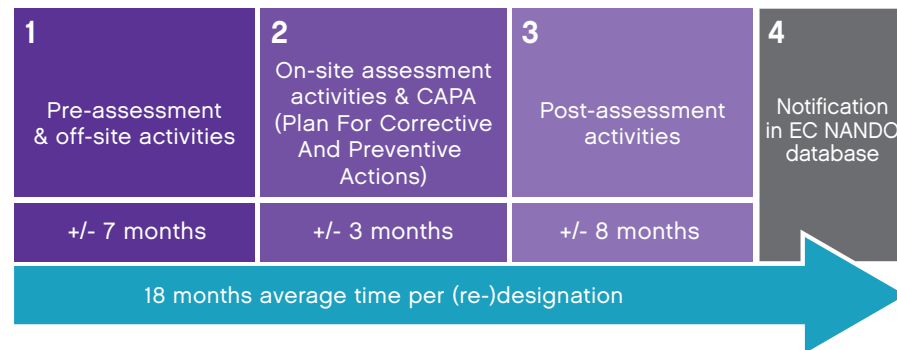


Countries can have a different amount of NBs: none, one or several

*EC NANDO database

(Re-)Designation of All Notified Bodies (NBs) Under the New Regulations

All existing and new Notified Bodies need to be designated to prove their competence in assessing products and quality systems under the increased requirements of the new regulations. This designation process includes four steps and is expected to take on average 18 months per Notified Body (source: NBOG).



The designation procedure started on 26 November 2017.

First Notified Bodies are expected to be designated in Q2/2019.

The Notified Body system will face a crunch time



- The new regulations came into force on 26 May 2017; the dates of application are 26 May 2020 for MDs and 26 May 2022 for IVDs.
- From the dates of application, only NBs that are designated for the new regulations can assess and (re-)certify products.
- Before that date, ~314.000 of 500.000 MDs and ~35.000 of 40.000 IVDs currently CE marked need to be (re-)certified to remain on the EU market.
- The 'grace period' does not solve the excessive work load that NBs face before May 2020 because:
 - many products are not eligible for the 'grace period';
 - eligible products would still need to be re-certified by May 2020.

What is the 'grace period'? It allows for certain devices to be placed on the market with a valid certificate based on the IVD/AIMD/MD Directives. This period starts from the date of application of the new Regulations to until 26 May 2024.

A Massive Increase in Notified Body (NB) Workload

Today

With 30% fewer NBs and tighter controls than in 2012, many NBs are already overstretched with (re-)certifications under the current IVD/AIMD/MD Directives, triggering delays in approval of products.

Tomorrow

NBs will have to follow additional and more stringent requirements under the new regulations (e.g. on clinical and post-market surveillance aspects). This will have further impact on the available time to review products.

Three main challenges



Lack of time

NBs have insufficient time between their designation and the dates of application of the new regulations to perform the required (re-)certification of products including:

- All CE marked products that are already on the market (re-certification);
- Products that will have Notified Bodies oversight for the first time (certification):
 - 85% of all IVDs;
 - Certain MD categories such as reusable surgical instruments;
- New and innovative products certification.



Lack of capacity

NBs need more capacity to absorb higher amounts of work. The current capacity challenge is further expanded because:

- None of the 59 existing NBs has yet been designated (as of July 2018);
- It is expected that not all 59 NBs will apply and succeed with the designation;
- Brexit risks to decrease the certification capacity by 30-40% that is currently carried out by UK Notified Bodies;
- NBs must continue to certify products while being (re-)designated to the new regulations.



Lack of available experts

NBs are facing challenges in finding, hiring and training staff to address the requirements of the new regulations:

- Additional expertise to check products against the new requirements is not sufficiently available;
- In-house staff has one to two years learning curve to be fully operational.



Too few appropriately staffed Notified Bodies will be available early enough to absorb the workload prior to the dates of application of the new regulations.

Foreseen Consequences



For manufacturers

- Impossibility today to file products for certification under the regulations until Notified Bodies are available;
- Lack of business predictability due to lack of clarity about which NB will have capacity at what point in time and for which product categories;
- Increased waiting time to obtain CE marking;
- Increased vulnerability and uncertainty for SMEs, which represent 95% of the sector;
- Disruption in the supply chain.



For patients, healthcare professionals, hospitals and laboratories

High risk of delay or discontinuation of access to medical technology products.



For the EU as a whole

Potential loss of competitiveness against other global constituencies (US, China, etc).

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