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Implementação MDR/IVDR

Panel IV - “Implementation MDR/IVDR”

A View from MedTech Europe

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Implementação MDR/IVDR

Medical Devices Regulation (MDR): In full application as of TODAY!

1. It is no longer possible to certify medical devices under the old Directives

2. The new regulatory system brings **strengthened requirements**. These requirements are important for **protecting patients** even further and **increasing trust** in the regulatory oversight of medical device safety and performance

3. Industry and regulators have worked hard since May 2017 to get MDR implementation to its current state, but we must all keep our foot on the accelerator for at least 3 more years

4. **To make 'MDR Chapter 2' a success and keep devices available to patients** beyond 26 May 2024, the sector must keep working to resolve **ongoing implementation challenges**
   - **Harmonisation between Member States**, e.g., on application of the EUDAMED database
   - **Notified Body capacity** to transition several thousand legal devices to MDR by May 2024
   - **Attractiveness of Europe versus other regions in terms of launching innovations**, in light of the overall clarity and predictability of the requirements, and the time to market

Implementação MDR/IVDR

in vitro Diagnostic Medical Devices Regulation (IVDR): A Ticking Time Bomb

1. Today, we start the **final year** of the 5-year transition period (May 2017 to May 2022)

2. If the MDR was an 'evolution' from the previous Directives, **the IVDR is a revolution**
   - 85% of all tests will need to undergo certification with a Notified Body for the first time
   - The strengthened requirements mean certification takes >12 months under the Regulation versus only 6 under the IVD Directive

3. Unfortunately, progress to deploy the regulatory infrastructure has been ***very*** limited, e.g.:
   - **Only 4 Notified Bodies** are designated, and they **report rapidly-dwindling capacity**
   - A significant number of manufacturers have **no** N**otified Body** at present
   - At the present rate, **barely 2-3 more** Notified Bodies are expected by May 2022…

4. **TIME IS UP! The system needs more time** if we are to keep IVDs available to patients
   - Since at least 2020, laboratories, healthcare professionals, hospitals, Notified Bodies and industry have all been calling for **comprehensive** solutions, e.g., prolonged transition time
   - The stakeholders have spoken...what is the response of the EU institutions?
   - Action is needed now to keep tests for **COVID-19**, **cancer**, **rare diseases and more** available

Thank you for your attention!

Let’s keep working together to make a success of the new regulatory framework for IVDs and medical devices!

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