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The new EU & EEA Medical Devices Regulations

MDR 2017/745
&
IVDR 2017/746

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Introduction

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- **2018 – on-going – Head of Quality and Regulatory -Otivio As**
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1. Introduction to the Legislation
2. Key Changes
3. Implementation Timelines
4. Notified Bodies (NBs)
5. Useful Links

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1. Introduction to the Legislation

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What do we know ?

Nothing more to do, just continue. On a precise way.

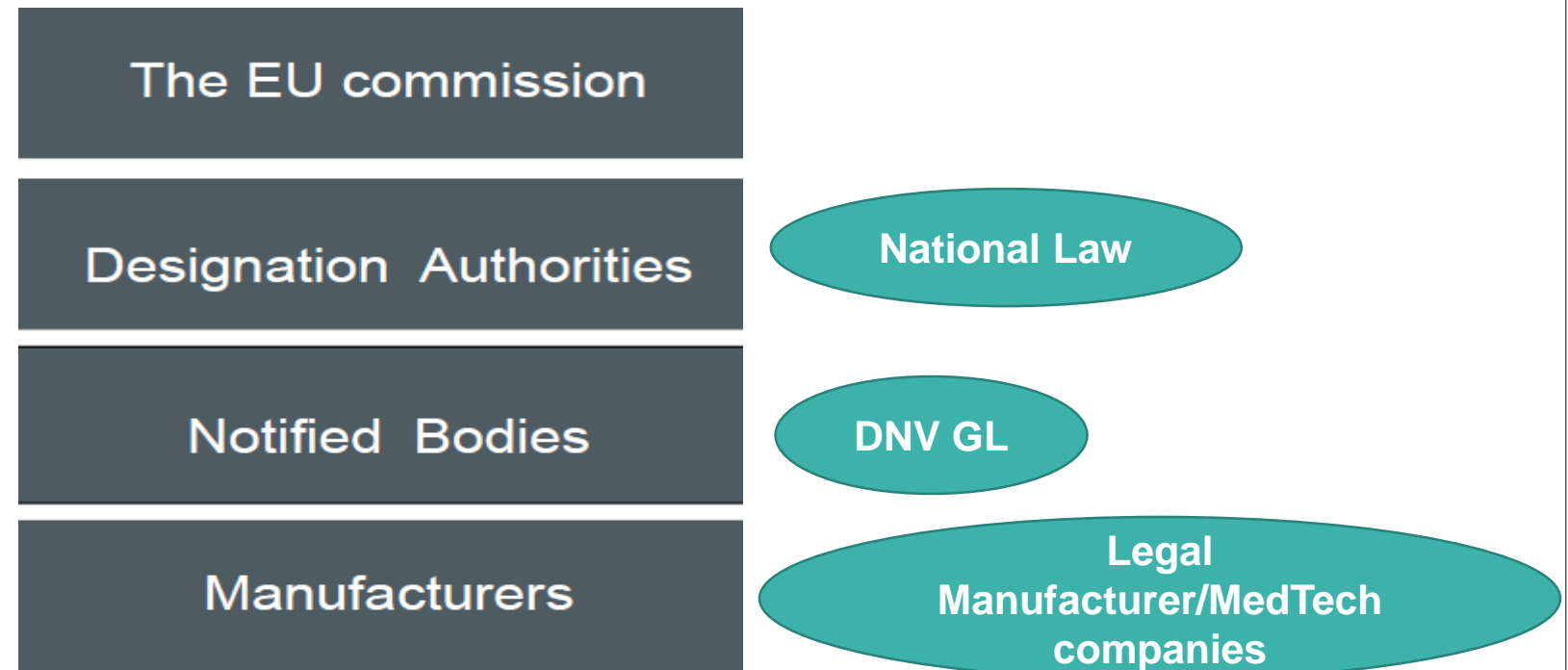
- Start with QMS (Quality Management System)
- QMS system exists
- If a company is ISO 13485 certified, then the standard mentions the word “Regulatory” 81 times in the standard and from section 4 to section 8 , its mentioned more precisely 44 times.
- If a company is not ISO 13485 or ISO 9001 certified even, then we need to follow MDR.

What does
this word
mean ?



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The Hierarchy



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New Regulations for Medical Devices

Council Directive 90/385/EEC on active implantable medical devices (AIMDD)

Council Directive 93/42/EEC on Medical Devices (MDD)



Regulations for Medical Devices (MDR 2017/745)

Regulation entered into force 26 May 2017

Regulation fully applies 26 May 2021

Council Directive 98/79/EEC on in-vitro diagnostic medical devices (IVDD)



Regulations for in-vitro diagnostic Medical Devices (MDR 2017/746)

Regulation entered into force 26 May 2017

Regulation fully applies 26 May 2022

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Legal Definition: Directive vs Regulation

- Regulations have binding legal force throughout every Member State and enter into force on a set date in all the Member States. (A Regulation must be implemented in full and without changes)

For example – MDR

-Food Information to Consumers Regulation 1169/2011

- Directives lay down certain results that must be achieved but each Member State is free to decide how to transpose directives into national laws

(A Directive is “transposed into national law with possibility of some changes”)

- In practice, there is no difference



Why new regulations?

➤ Introduced in response to:

- Scientific advances since 1993
- Series of scandals (particularly PIP, named on Commission website)
- Demand to improve legal system for regulation
 - Divergences in application of the rules across the EU
 - Perceived weaknesses in control of Notified Bodies

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Background: Scandals

- <https://www.nhs.uk/conditions/pip-implants/>
- <https://www.france24.com/en/20180929-french-pip-breast-implants-scandal/>
- <https://www.bmj.com/company/newsroom/investigation-exposes-vaginal-mesh-scandal-that-has-left-thousands-of-women-irreversibly-harmed/>
- <https://www.massdevice.com/pip-breast-implant-scandal-story-triggered-change/>

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2. Key Changes

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OVERVIEW OF REGULATIONS MAIN CHANGES (MDD TO MDR)



MDD

MDR

20 Articles

60 Pages

12 Annexes

10 Chapters

123 Articles

175 Pages

17 Annexes

Regulation

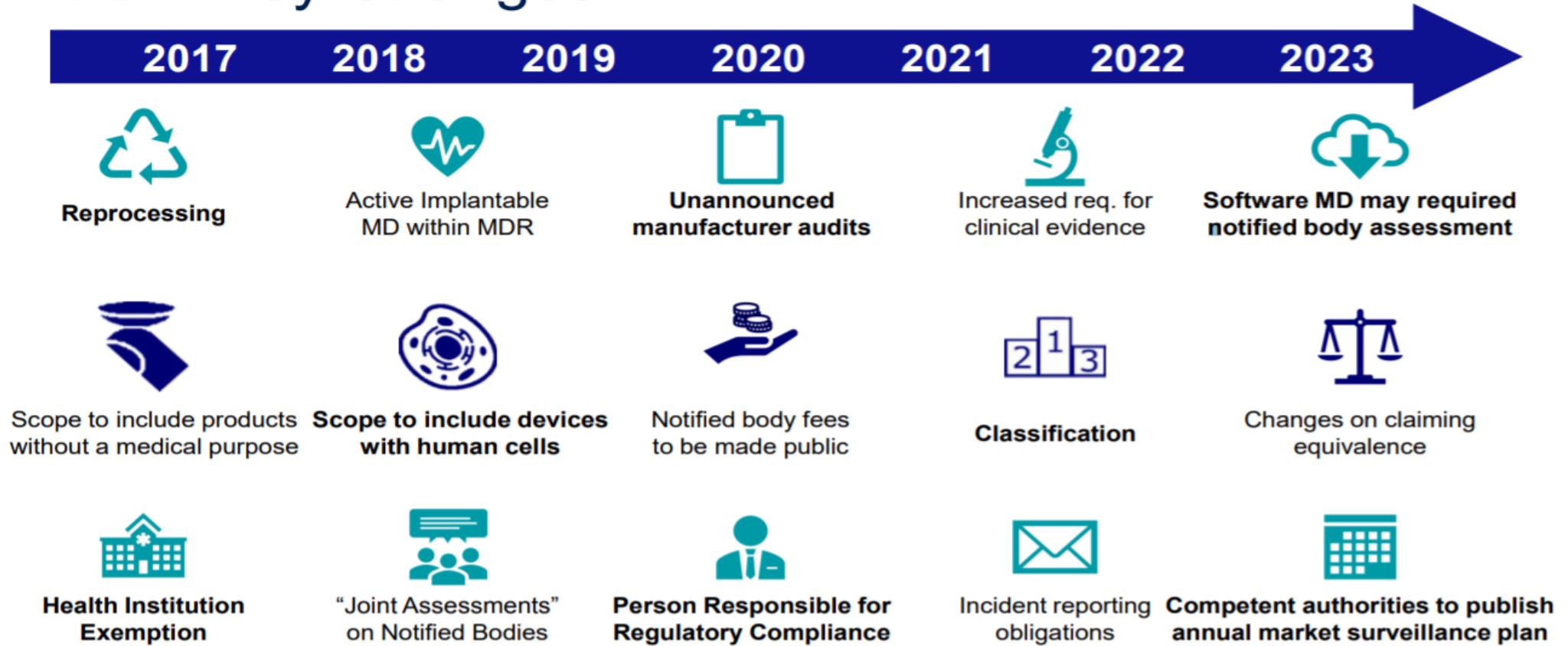
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Overview of Regulations Main changes (MDD to MDR)

- Directive (MDD) will change into Regulation (MDR)
 - Stricter control of medical devices (risk management, clinical evaluation, technical reports, etc.)
 - Enforced requirements regarding MDR
 - Compared to the MDD, the MDR promotes a shift from the pre-approval stage (i.e., the path to CE Marking) to a life-cycle approach.
 - Reinforcement of oversight of Notified Bodies
 - In Annex I – General Safety and Performance Requirements replaces the current Essential Requirements – (94 new requirements)
- Legal Manufacturer need to provide evidence for the requirements
- More stringent requirements to provide technical documentation and clinical evidence (MDR, Annex II); Aligned with ISO13485 2016

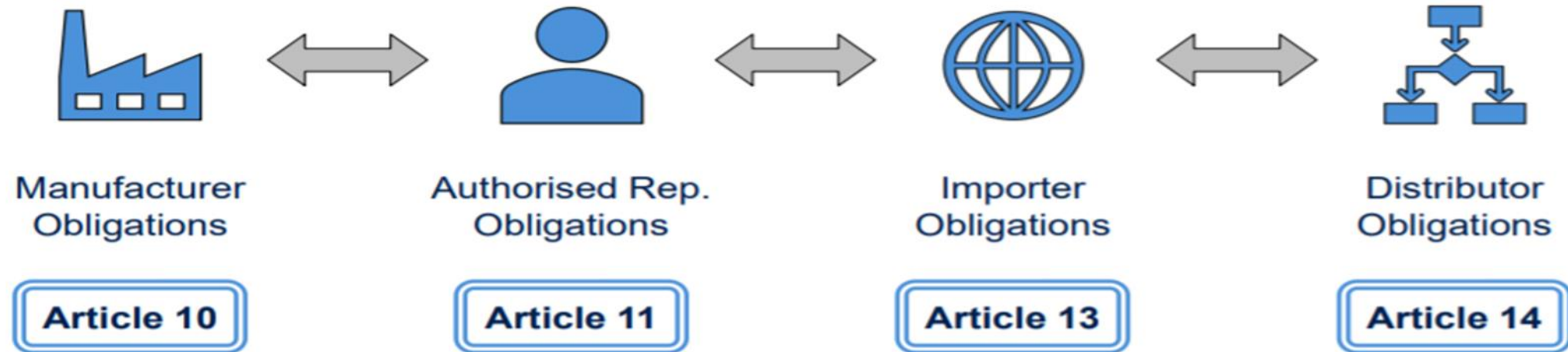
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MDR Key Changes



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The Supply Chain



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Traceability - Eudamed



What is EUDAMED?
European Database on Medical
Devices.

Deadline for Implementation 25
March 2020.

Article 123 (3d): If EUDAMED is
not fully functional on 26 May
2021, the obligations and
requirements that relates to
EUDAMED shall apply 6 month
after publication of the notice
referred to Article 34(3)).

Article 34

Functionality of Eudamed

1. The Commission shall, in collaboration with the MDCG, draw up the functional specifications for Eudamed. The Commission shall draw up a plan for the implementation of those specifications by 26 May 2018. That plan shall seek to ensure that Eudamed is fully functional at a date that allows the Commission to publish the notice referred to in paragraph 3 of this Article by 25 March 2020 and that all other relevant deadlines laid down in Article 123 of this Regulation and in Article 113 of Regulation (EU) 2017/746 are met.
2. The Commission shall, on the basis of an independent audit report, inform the MDCG when it has verified that Eudamed has achieved full functionality and Eudamed meets the functional specifications drawn up pursuant to paragraph 1.
3. The Commission shall, after consultation with the MDCG and when it is satisfied that the **conditions referred to in paragraph 2** have been fulfilled, publish a notice to that effect in the Official Journal of the European Union.

Traceability – UDI



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Article 123g concerning Unique Device Identifier (UDI) updated.

Implementation dates are moved two years

Better aligned when EUDAMED enter into force

With regards to reusable devices that are required to bear the UDI carrier on the device itself, Article 27(4) shall apply to:

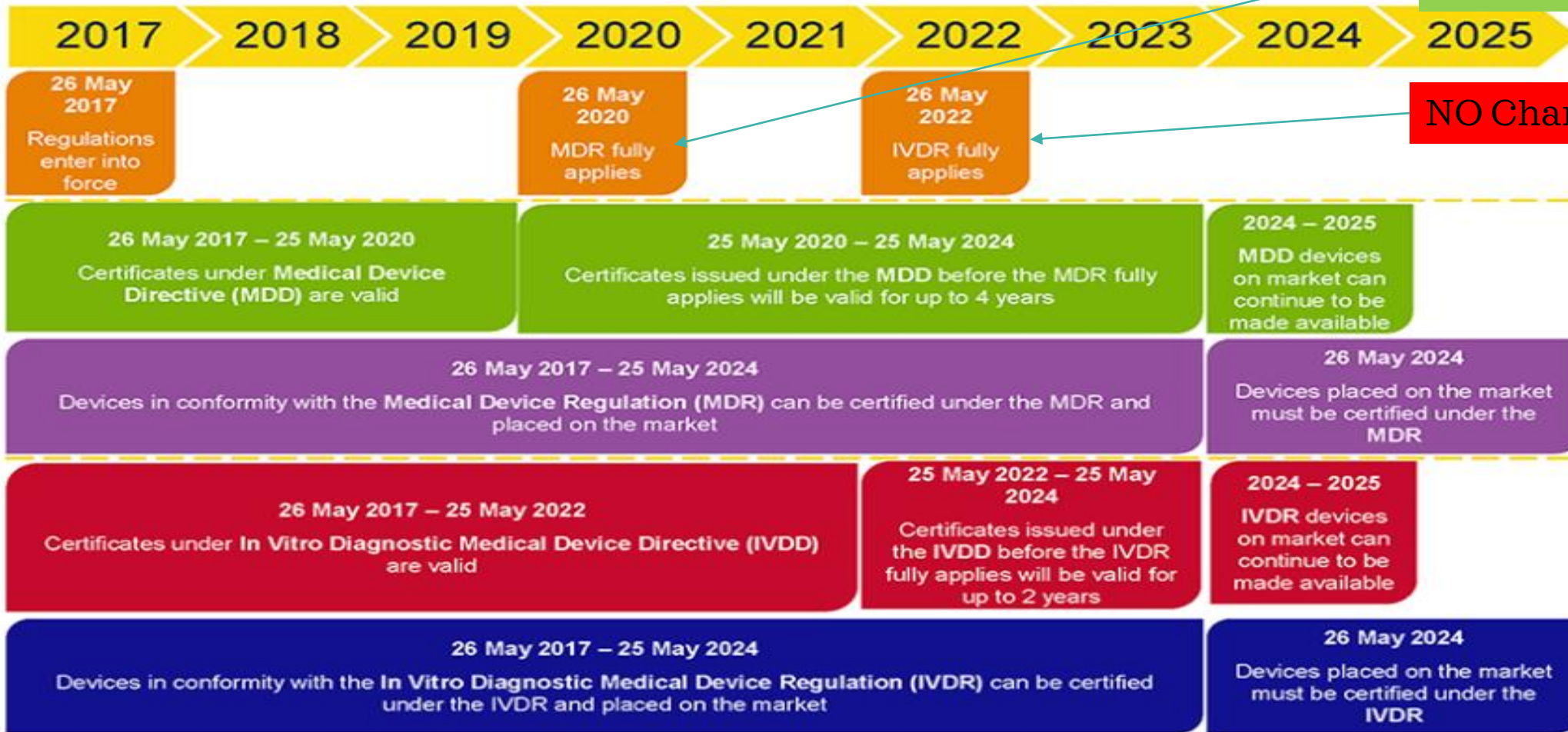
- i. Implantable devices and class III from 26 May 2023
- ii. Class IIa and class IIb devices from 26 May 2025
- iii. Class I device from 26 May 2027

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3. Implementation Timelines

Placing a device on the market under the new Regulations Transition Details + Timeline

26 May 2021
COVID-19



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4. Notified Bodies (NBs)

Notified Bodies (NBs)



- Several NBs have lost their license/part of a license to operate
- Extremely tough assessments with participants from commissions and authorities with high expertise. MDD/AIMD/IVD 80 to 58
- Several deviations to handle
- 4000 certificates need re-certification.
- New Start-up companies want NBs services
- NBs are fully booked.
- Tougher reviews of technical files and audits.



Notified bodies
Nando

Country

Legislation

Body

Construction products

Free search

Mutual Recognition Agreements

CETA Protocol on Conformity Assessment

Notifying Authority - Notification procedures

Accreditation Body

Glossary

Single Market and Standards - links

News

Events

Tools and Databases ✓

Contracts and grants ✓

Public consultations

Publications

Bodies

Found : 13

Search criteria :

Legislation : Regulation (EU) 2017/745 on medical devices

Procedure / Article or annex :

Products :

Horizontal technical competence :

[Search](#)

Withdrawn/Expired/Suspended Notifications/NBs are not displayed in this list, you can find them in the Body module under the hyperlink "[Withdrawn/Expired/Suspended Notifications/NBs](#)"

Body type ▲	Name ▲	Country ▲
• NB 0086	BSI Assurance UK Ltd	United Kingdom
• NB 2797	BSI Group The Netherlands B.V.	Netherlands
• NB 2409	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.	Hungary
• NB 1912	DARE!! Services B.V.	Netherlands
• NB 0344	DEKRA Certification B.V.	Netherlands
• NB 0124	DEKRA Certification GmbH	Germany
• NB 2460	DNV GL Presafe AS	Norway
• NB 0051	IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.	Italy
• NB 0483	MDC MEDICAL DEVICE CERTIFICATION GMBH	Germany
• NB 0482	MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH	Germany
• NB 0050	National Standards Authority of Ireland (NSAI)	Ireland
• NB 0197	TÜV Rheinland LGA Products GmbH	Germany
• NB 0123	TÜV SUD Product Service GmbH Zertifizierstellen	Germany

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MDR STATUS NOTIFIED BODIES

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5. Useful Links

Links

https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02017R0745-20170505&from=EN>

<https://www.standard.no/>



Challenges and Impact on MedTech industry

- New rules might prevent the fraud seen in PIP case
- New rules will strengthen oversight of NB's
- Review times and costs will increase
- ✓ Costs will ultimately be passed through to payers (End Customers)
- ✓ Smaller EU focused companies & start-ups may struggle
- ✓ Class III Implantable effectively have 2 reviews: More complex than a new drug approval
- All current Notified Bodies may not be able to meet requirements
- ✓ Finding qualified and non-conflicted staff
- Increased internal costs on post-market surveillance and clinical evaluation updates
- Mature, legacy products may be discontinued due to compliance remediation costs



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