New EU rules to ensure safety of medical devices

From Directive to Regulation (MDR/IVDR)

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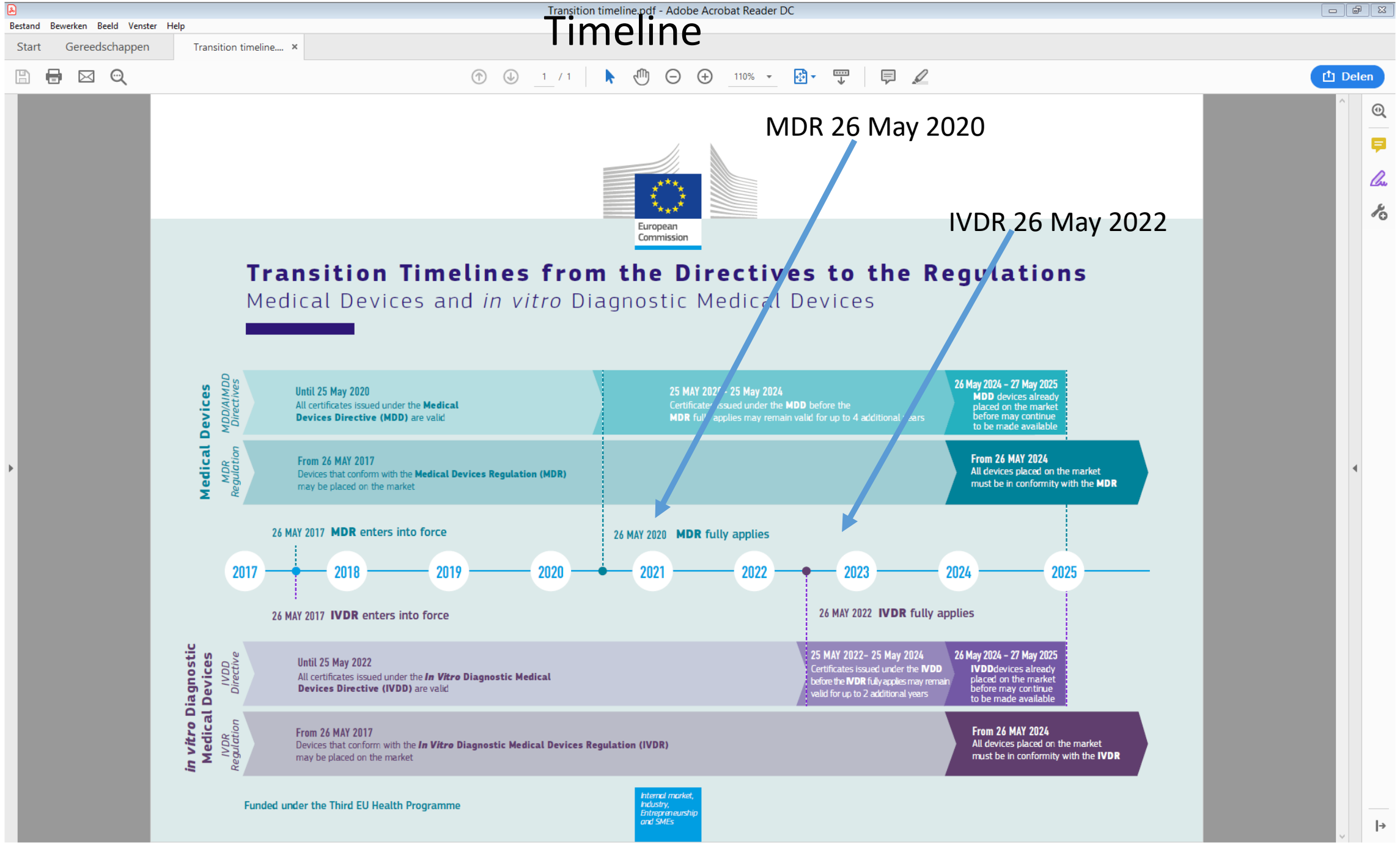
Definitions

- MDD = Medical Device Directive (1993)
- MDR = Medical Device Regulation
- IVDR = In Vitro Diagnostics Regulation

Why is this important for you?

1. New and stronger rules for introduction MD's in patient care
2. More transparency and traceability by:
    1. Comprehensive EU database (EUDAMED) with an actual picture of the lifecycle of all products on the EU market
    2. Device identification system based on a unique device identifier (UDI)
    3. Implant card for patients about implanted medical devices
3. Changes in classification (I, II, III)
    1. IVD's
    2. Software (app, EPR)
    3. Reusable instruments (surgery!)

Timeline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MDR 26 May 2020
IVDR 26 May 2022
European Commission
Transition Timelines from the Directives to the Regulations
Medical Devices and in vitro Diagnostic Medical Devices
Medical Devices
MDD/AIMDD Directives
Until 25 May 2020
All certificates issued under the Medical Devices Directive (MDD) are valid
25 MAY 2020 - 25 May 2024
Certificates issued under the MDD before the MDR fully applies may remain valid for up to 4 additional years
26 May 2024 - 27 May 2025
MDD devices already placed on the market before may continue to be made available
MDR Regulation
From 26 MAY 2017
Devices that conform with the Medical Devices Regulation (MDR) may be placed on the market
From 26 MAY 2024
All devices placed on the market must be in conformity with the MDR
26 MAY 2017 MDR enters into force
26 MAY 2020 MDR fully applies
2017 2018 2019 2020 2021 2022 2023 2024 2025
26 MAY 2017 IVDR enters into force
26 MAY 2022 IVDR fully applies
in vitro Diagnostic Medical Devices
IVDD Directive
Until 25 May 2022
All certificates issued under the In Vitro Diagnostic Medical Devices Directive (IVDD) are valid
25 MAY 2022- 25 May 2024
Certificates issued under the IVDD before the IVDR fully applies may remain valid for up to 2 additional years
26 May 2024 - 27 May 2025
IVDDdevices already placed on the market before may continue to be made available
IVDR Regulation
From 26 MAY 2017
Devices that conform with the In Vitro Diagnostic Medical Devices Regulation (IVDR) may be placed on the market
From 26 MAY 2024
All devices placed on the market must be in conformity with the IVDR
Funded under the Third EU Health Programme
Internal market, Industry, Entrepreneurship and SMEs

Check EU website: get ready for the new regulations!

Single market and standards | Industry | Entrepreneurship and SMEs | Access to finance for SMEs | Sectors

Medical Devices

- New Regulations
- Current Directives
- Scientific and Technical Assessment
- International Cooperation
- Library
- Contacts

Medical devices - links

- News
- Events
- Tools and Databases
- Contracts and grants
- Public consultations
- Publications

Medical Devices

Medical devices make an essential contribution to healthcare in the EU for the benefit of European citizens. From sticking plasters to X-ray scanners, dentures to hip joints and in-vitro diagnostic devices that monitor diabetes or identify infections; medical devices are crucial in diagnosing, preventing, monitoring and treating illness, and overcoming disabilities. They are also important to the economy, providing €110 billion in sales and 675,000 jobs in Europe. The EU is a net exporter in this sector.

Highlights

- UDI system frequently asked questions and answers
- Call for observers of the medical devices coordination group's nomenclature sub-group
- Call for clinical and other experts to be published later in 2019
- The Commission designates entities to operate a system for assignment of unique device identifiers (UDIs)
- EUDAMED device data elements' registration timeline
- EUDAMED legacy devices' registration
- Further guidance: regulation of medical devices if there's no Brexit deal
- Using the UKCA marking if the UK leaves the EU without a deal

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Reasons for development of new MDR

- 1990s: harmonisation of current rules on safety and performance of medical devices
  →CE mark (1993); class I, IIa, IIb, III
- 2000-2020:
  - substantial technological and scientific progress
  - Improvement of safety of medical devices necessary
- Examples:
  - Breast implants
  - Metal hips
  - Fillers
  - Software (apps)
- Patient safety; public health

Most important changes (from a Dutch view)

- Hospital/patient care
  - Risk management/post marketing surveillance
    - Registry of incidents not only by authorities but also in cooperation with manufacturers (‘clinical file’)
  - MD’s and IVD’s developed in hospitals, for their own use, also must comply with the new MDR/IVDR
    - Authorities view hospitals as manufacturer
  - Modification/repairment of MD’s by hospital technicians can result in a change in intended use of the MD
    - Authorities view hospitals as manufacturer
  - Implant card for patients

4 Risks

- Post marketing surveillance:
  - Manufacturers ask hospitals continuously for clinical data/findings.
  - New balance necessary between lot of regulations and practical approach
- Main manufacturers reduces drastically their product port-folio
- Small manufacturers don’t have time/energy/resources to get a CE-mark by the notified bodies just in time (before May 26th)
- Few notified bodies available in Europe; loss of expertise.
- Higher product prices, especially expected for IVDR

5 Next steps

- Discuss impact of MDR with most important manufacturers
  - Cooperation of procurement/Medical physics/Expert med instrumentation
  - Items: availability MD’s, validity of current CE mark, costs (!)
- Documentation, especially on high risk MD’s
  - Risks
  - Maintenance and spare parts
  - Reasons for deviations
- Central registry of problems
- Maintaining Convenant Medische Technologie (life-cycle approach)

Get ready for the new regulation!

- Each hospital has its own responsibility to prepare the change
- Check with your procurement your productportfolio
- Perform an inventory on the potential risks if you develop your own devices and medical products

Thank you for your attention!