




# **Introduction to the new regulatory framework for medical devices and *in vitro* diagnostic medical devices**

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# Key figures

- 500 000 employees
- 25 000 companies (>80 % SMEs)
- 100 billion € annual sales
- 8-10% of annual sales invested in R&D
- 5-10% of healthcare spending
- Innovation driven (life cycle ~ 18 months)

# Revision of the EU Medical Devices Legislation - Background



Directive 90/385/EEC on active implantable medical devices  
Directive 93/42/EEC on medical devices



**Proposal for a Regulation on medical devices**

Directive 98/79/EC on in vitro diagnostic medical devices



**Proposal for a Regulation on in vitro diagnostic  
medical devices**

## State of play and timeline

- 26 September 2012: adoption of the two Commission proposals on medical devices and IVDs
- Adoption of the Council's first reading position 7 March 2017
- EP second-reading vote 4 April 2017
- Entry into force on the twentieth day after its publication in the OJ
- Date of application: from three (MD)/five (IVD) years after entry into force

# Key derogations (1)

## 6 months after entry into force

- Requirements on Notified Bodies
- Designation of Competent Authority
- Establishment of the MDCG

## 12 months after entry into force

- Cooperation among Competent Authorities

## 18 months before the date of application

- Designation of reference laboratories for IVDs

## Key derogations (2)

### 0-18 months after the date of application

- Registration of devices

### 0-7 years after the date of application

- Coordinated procedure for clinical investigation

### 2/4 years after date of application

- Certificates issued under old Directives: maximum period of validity of 4 years (MD) and 2 years (IVD) after entry into application

### 3/5 years after date of application

- Devices lawfully placed on the market under old Directives prior to the date of application may continue to be made available on the market or put into service until five years (IVD three years) after that date.

# Objectives of the Regulations

- **Extension and clarification of the scope**
- **Updated classification rules**
- **Stricter designation rules and oversight of Notified Bodies**
- **Enhanced powers of Notified Bodies**
- **Scrutiny for high risk devices**
- **Clearer obligations and responsibilities for economic operators**
- **Harmonised rules on reprocessing of single use devices**
- **Stricter requirements regarding clinical evidence**
- **Reinforced rules on vigilance and market surveillance**
- **Improved EU database (EUDAMED) and transparency**
- **Better traceability of devices (UDI)**
- **Enhanced coordination between national authorities**

# Clinical evaluation for MD

- **Critical evaluation of the relevant scientific literature**
- **Critical evaluation of available clinical investigations**
- **Consideration of available alternative treatments**
- **Clinical evaluation report**



# Clinical investigation for MD

- **Shall be performed for implantable devices and class III devices**
- **Exceptions:**
  - Modification of a device already manufactured by the same manufacturer
  - The modified device is equivalent to the marketed device
  - The clinical evaluation of the marketed device is sufficient
    - The NB shall check that the PMCF plan is appropriate and includes post market studies
  - Sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plzates, wires, pins, clips or connectors

# Scrutiny for MD (1/3)

- Clinical evaluation consultation procedure for class III implantable devices and class IIb active devices intended to administer and/or remove medicinal product to or from the body if this is done in a manner that is potentially hazardous (rule 12)
  
- Exceptions:
  - Renewal of a certificate under the Regulation;
  - Modified device by the same manufacturer for the same intended purpose and not affecting the benefit/risk ratio;
  - Clinical evaluation is in compliance with relevant Common specifications,

## Scrutiny for MD (2/3)

- The Notified body send its clinical evaluation assessment report + manufacturers' clinical evaluation document to the Commission
- The clinical evaluation assessment report set out the conclusion of the NB concerning the clinical evidence (including benefit/risk determination) and the consistency with the intended purpose
- Expert panel to decide whether it will provide a scientific opinion within 60 days (or not to provide an opinion within 21 days) based on:
  - The novelty of the device and the possible major clinical or health impact;
  - Significant change in the benefit/risk profile of the device due to scientifically health concerns or the impact on health in case of failure of the device;
  - Significant increase rate of serious incidents,

## Scrutiny for MD (3/3)

- Scientific opinion of the expert panel shall be taken into consideration by the NB
- If necessary, the NB shall advise the manufacturer:
  - To restrict the intended purpose of the device to certain groups of patients or certain medical indication;
  - Limit the duration of the certificate;
  - Undertake post market clinical follow-up studies;
  - Impose restrictions as appropriate.
- The NB shall provide a justification where it has not followed the advice of the expert panel;
- Scientific opinion and justification of the NB are publicly available on Eudamed.
- If no opinion delivered within 60 days: NB can deliver certificate

# Post-market surveillance system

- Gather, record and analyse relevant data on the quality, performance and safety of devices, to draw the necessary conclusions and determine any preventive and corrective actions
  - **Post-market surveillance plan**
  - **Post-market surveillance report (Class I)**
  - **Periodic safety update report (Class IIa, IIb and III)**
  - **Trend reporting**

# IVD Conformity assessment

- **Class D:**
  - ✓ if designated, **Reference Laboratory** to verify claimed performance and compliance with the applicable Common Specifications (laboratory tests)
  - ✓ If **no Common Specifications and first certification for that type of device**: application of the **'scrutiny mechanism'** (consultation of expert panel)

**Thank you for your attention!**

**European Commission  
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