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EU Medical Device Regulation

New Laws and Regulations on both Sides of the Pond

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Agenda

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II. EU Medical Device Regulation

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I. Current Regulatory Regime EU

Current Regulatory Regime for Medical Devices in the EU

I. EU MDD / Guidelines (1)

- Provisions on EU level
  - Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices
  - Directive 93/42/EEC concerning medical devices
  - Directive 98/79/EC on in-vitro diagnostic medical devices
- Commissions Guidelines:

List of Guidance MEDDEVs

See below a complete list of all Guidance Meddevs, including links to further information:

	Title
2.1 Scope, field of application, definition	MEDDEV 2.1/1 (18 kB) Definitions of "medical devices", "accessory" and "manufacturer" **April 1994**
	MEDDEV 2.1/2 rev.2 (14 kB) Field of application of directive "active implantable medical devices" **April 1994**
	MEDDEV 2.1/2.1 (12 kB) Treatment of Computers Used to Program Implantable Pulse Generators **February 1998**

I. EU MDD / Guidelines (2)

- EU Medical Device Directives require implementation into national law (in each member state)

  ⇒ German Medical Device Act (cf. www.bundesgesundheitsministerium.de; English version)

  ⇒ High degree of regulatory harmonisation among the EU markets

- In contrast, no EU-wide harmonisation regarding
  - reimbursement,
  - product-related advertisement, and
  - interactions with healthcare professionals / patient organisations.

II. EU MDR: Why and When

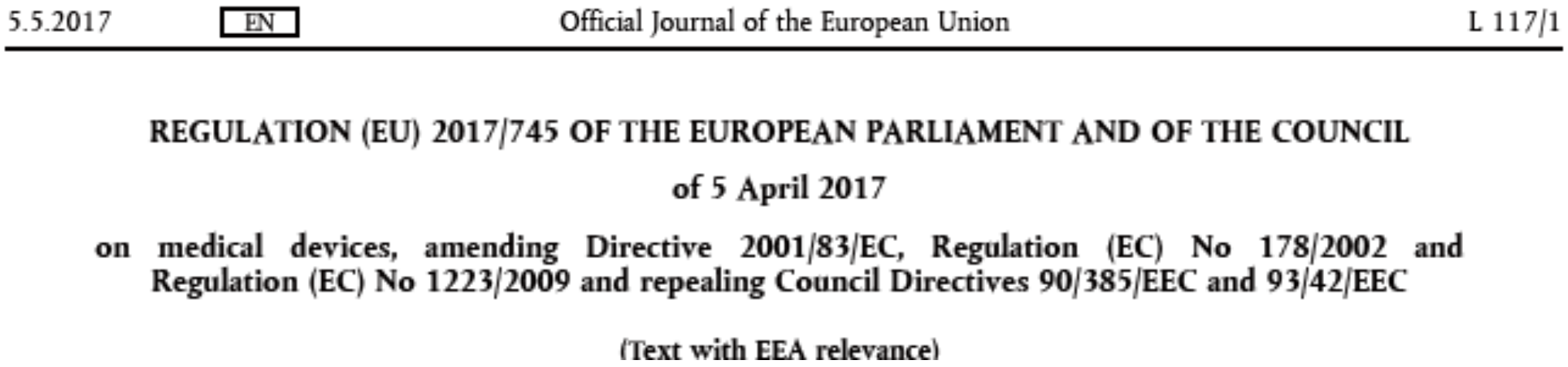
2.1 EU MDR: Why and When?

II. EU MDR: Why and When? (1)

- Motivation / Reason for a new EU-wide regulatory regime
  - PIP Scandal (*Poly Implant Prothèse*; March 2010)
  - However, Commission started already 2003/2009 the so called „MDD Recast“ initiative in order to strengthen patient and user safety / competitive position EU industry / innovations / internal market / transparency / etc.

- MDD Recast (2003) until MDR (May 2017): Why 14 / 17 years?
  - Extent/quantity: MDR 23 Articles/10 Annex vs. MDR 123 Articles/17 Annexes
  - EU Parliamentary elections in May 2014 (principle of discontinuity)
  - First draft MDR (2012) until publication EU Journal 9 EU Council Presidency
  - Stricter regulatory framework provokes lobbying

II. EU MDR: Why and When? (2)



5.5.2017 EN Official Journal of the European Union L 117/1

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 5 April 2017

on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

(Text with EEA relevance)

⇒ **Regulation** (EU) 2017/745 replaces **Directive** 90/385/EWG (active implantable MD) and **Directive** 93/42/EWG ("normal" MD)

⇒ Publication EU Journal 5 May 2017

⇒ Enters into force 20 days after publication

⇒ Effective date: 26 May 2017 (Article 123 [1] Regulation [EU] 2017/745; „**MDR**")

2.2 EU MDR: Transitional Periods CE-marks

II. EU MDR: Transitional Periods CE-marks (1)

Transitional Provisions:

- **MDR** regulated in Article 123 (2) MDR:

  „It shall apply from 26 May 2020.“

- **Notified Bodies** regulated in Article 120 (1) MDR:

  „From 26 May 2020, any publication of a notification of a notified body (…) shall become void.”

- **CE-marks** regulated in Article 120 (2) and (4) MDR:

  “Certifications issued (…) from 25 May 2017 shall remain valid until the end of the period indicated on the certificate, (…). They shall however become void at the latest on 27 May 2024”

  “Devices lawfully placed on the market (…) prior to/after 26 May 2020, may continue to be made available on the market or put into service until 27 May 2025.”

2.3 EU MDR: Check your Notified Body

II. EU MDR: Check your Notified Body (1)

- In contrast to the US, medical devices do not require a marketing authorisation from an authority in the EU
  - Notified body executes conformity assessment procedure
  - „Declaration of Conformity“ confirms compliance with safety requirements set out in MDD (or MDD)
  - Valid for 5 years before re-certification is necessary
- Notified Bodies are private companies
  - Upcoming problem of so called “orphaned manufacturers”?
  - NB as an endangered species?
  - *„From 26 May 2020, any publication of a notification of a notified body (…) shall become void.”*

II. EU MDR: Check your Notified Body (2)

Status quo under MDD (October 2019, **Germany**):

Legislation :

93/42/EEC Medical devices

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 0044	TÜV NORD CERT GmbH	Germany
NB 0123	TÜV SÜD Product Service GmbH Zertifizierstellen	Germany
NB 0124	DEKRA Certification GmbH	Germany
NB 0197	TÜV Rheinland LGA Products GmbH	Germany
NB 0297	DQS Medizinprodukte GmbH	Germany
NB 0481	ecm-Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH	Germany
NB 0482	MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH	Germany
NB 0483	MDC MEDICAL DEVICE CERTIFICATION GMBH	Germany
NB 0494	SLG PRÜF UND ZERTIFIZIERUNGS GMBH	Germany
NB 0633	Berlin Cert Prüf- und Zertifizierstelle für Medizinprodukte GmbH	Germany
NB 0681	Eurofins Product Service GmbH	Germany

II. EU MDR: Check your Notified Body (3)

Status quo under MDR (October 2019, **EU**):

Legislation :

Regulation (EU) 2017/745 on medical devices

Body type	Name	Country
NB 0086	BSI Assurance UK Ltd	United Kingdom
NB 0124	DEKRA Certification GmbH	Germany
NB 0051	IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.	Italy
NB 0197	TÜV Rheinland LGA Products GmbH	Germany
NB 0123	TÜV SÜD Product Service GmbH Zertifizierstellen	Germany

=> EU-wide in 2010 **NBs 80+**, in 2013 **NBs 58**, in 2019 **NBs 39**, currently 5 with MDR notification, after May 2020 **?**

2.4 New Classification Rules

II. EU MDR: New Classification Rules (1)

- Risk-based approach for classification of medical devices
- Different requirements for class I, I sterile, I measure, IIa, IIb and III:

Conformity assessment is the method by which a manufacturer demonstrates that their devices comply with the requirements of Directive 93/42/EEC. The classification of the medical device will have an impact on the conformity assessment route that the manufacturer should follow in order to affix the CE marking on the medical device.

CONFORMITY ASSESSMENT PROCEDURES	CLASSES					
ANNEXES	I	I Sterile	I measure	IIa	IIb	III
II (+ section 4)						√
II (- section 4)		√	√	√	√	
III					√	√
IV		√	√	√	√	√
V		√	√	√	√	√
VI		√	√	√	√	
VII	√	√	√	√		

MEDDEV 2.4/1 rev.9 (June 2010)

II. EU MDR: New Classification Rules (2)

The following devices are subject to an "upgrade" (Annex VIII MDR):

- Implantable medical devices (class IIb; Rule 8)
- Software (class IIa; Rule 11, i.e. NB required)
- Medical devices incorporating/consisting of nanomaterials (class III; Rule 19)
- Medical devices composed of substances which are intended to be introduced into the human body (class III, and IIb; Rule 21)

2.5 EU MDR: Person Responsible for Regulatory Compliance (PRRC)

II. EU MDR: PRRC (1)

- Function already exists under MDD for manufacturers located in Germany and Austria (so called safety inspector)

- Now EU-wide acc. to Article 15 MDR:

  "Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance who possesses the required expertise in the filed of medical devices"

- Required qualification is either:
  - university degree in medicines, pharmacy, or engineering, or
  - four years of professional experience in RA or QMS

II. EU MDR: PRRC (2)

- Function of PRRC can be outsourced in case of SME (“*permanently and continuously at their disposal*”) and authorised representatives

- Minimum responsibilities of PRRC (acc. to Article 15 (3) MDR):
  - Review of conformity with QMS and release of devices
  - Keeping up-to-date DoC and technical documentation
  - Fulfil manufacturer´s post-market surveillance obligations
  - Reporting serious incidents
  - Implementing and executing field safety corrective actions

II. EU MDR: Obtaining CE-marks under MDR

2.6 EU MDR: Higher Burden for Obtaining CE-marks under EU MDR

II. EU MDR: Obtaining CE-marks under MDR (1)

- Stricter requirements for obtaining CE-marks under the new regime

- MDD requires / required mainly safety of the medical device (cf. Article 2 MDD):

  "Member states shall (…) ensure that devices may be placed on the market only if they comply with the requirements laid down in this Directive (…)"

- MDR requires also evidence of efficacy (in view of the intended purpose, Article 5 MDR) before a device may be placed on the market / put into service

II. EU MDR: Obtaining CE-marks under MDR (2)

Article 5

Placing on the market and putting into service

1. A device may be placed on the market or put into service only if it complies with this Regulation when duly supplied and properly installed, maintained and used in accordance with its intended purpose.

2. A device shall meet the general safety and performance requirements set out in Annex I which apply to it, taking into account its intended purpose.

3. Demonstration of conformity with the general safety and performance requirements shall include a clinical evaluation in accordance with Article 61.

Article 2

Definitions

(44) 'clinical evaluation' means a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer;

2.7 EU MDR: What else…?

II. EU MDR: Legal Obligations Manufacturers (1)

- MDR provides for an extensive list of (general) legal obligations for manufacturers (Article 10 [1] to [16])

- Legal definition of manufacturer now also includes Private Labelling (cf. Article 2 MDD):

  "***Manufacturer means a natural or legal person who manufacturers*** *or fully refurbishes a device or has a device designed, manufactured or fully refurbished,* ***and markets that device under its own name or trademark.***"

- Obligations:
  - Conformity assessment procedure
  - QMS

II. EU MDR: Legal Obligations Manufacturers (2)

Obligations:

- Provide for technical documentation and affix CE mark in the device
- Conduct of clinical evaluation
- Create UDI, on the label or packaging, registration at EUDAMED
- Implementation of post-market surveillance system
- System for recording and reporting incidents and fsca
- Provide for financial coverage in respect of their financial liability
- (…)

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