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EU Device Regulations

A Work in Progress

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EU Device Regulations

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Four Freedom Principles: Movement of

- Services
- Capital
- People
- Products

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EU Device Regulations

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1. Medical Device Directive 93/42/EEC

2. Packaging and Packaging Waste Directive 94/62/EC

3. Waste Electrical and Electronic Equipment Directive 2002/96/EC (**WEEE**)

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Which Directive?

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- Medical Device (MDD)
- Active Implantable Medical Device (AIMD)
- In-Vitro Diagnostics (IVDD)
- Medicinal Products Directive (MPD)

The definition determines the scope!

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Basic Steps to Compliance - MDD

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- Within the scope of which Directive?
- **Classification**
- Conformity Assessment Route
- Compliance to the **Essential Requirements**
- Harmonized standards
- Technical File

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Basic Steps to Compliance - MDD

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- Risk assessment
- Notified Body
- **Authorized Representative** and Competent Authority registration
- Vigilance system and Post Market Surveillance
- **CE Marking**
- Declaration of Conformity

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The Medical Device Directive CE

Upcoming changes to the MDD and how they might impact your company.

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Active Implantable Devices

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- AIMDD adopted in 1990 prior to the MDD and IVDD
- Updates bring AIMDD in line with the MDD
- References to the Authorized Representative (EC REP)
- References to European databank
- Application of Directive 2000/70/EC on human blood derivatives

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Authorized Representative – EC REP

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- Some Competent Authorities still believe EC REP is responsible for the product
- New MDD explicitly states need for EC REP for all classes of devices
- EC REP will also be mandated to be the contact point for regulatory issues in lieu of the manufacturer

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Borderline Products

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- Currently, these are classified by Intended Use rather than Primary Mode of Action
- Examples: Pre-filled drug syringe
  - Intended use: Both a device (syringe) and the drug
  - Primary Mode of Action: Definitely a drug

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Combination Devices

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- Applies to medicinal products which "form a single integral product intended solely for use in the given combination and is not reusable"
- These will be governed by Directive 2001/83/EEC
- Annex 1 will govern safety and performance
- *DRAFT MEDDEV 2. 1/3 rev 3*

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Clinical Data

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- Now required for ALL devices, including Class 1
- More stringent requirements as to what constitutes “clinical evidence”
- Mandates stronger enforcement by authorities
- Annex 10 significantly changed

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Conformity Assessment

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- Mostly affects Class 1 Sterile and Measuring devices
- More flexibility to select a conformity assessment route to compliance

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Central Circulatory System

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- **Will now include the vessels aortic arch *(arcus aortae)* and descending aorta (*aorta descendens)* to the aortic bifurcation (*bifurcatio aortae)*.**
- **Devices that come into contact with these vessels will be considered Class 3**

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"Continuous Use" definition

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- Now will include situations where a device, upon discontinuation or removal, is immediately replaced with another device
- Could result in up-classification

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eLabeling

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- Upcoming changes to the MDD open the door for e-labeling
- What might be allowed?
  - CD-ROM
  - Website IFU
- Professional use versus consumer use
- Most important: Consider risk to user, not just cost savings for you!
- New MEDDEV 2.14/3 rev 1 – IVD

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Ergonomics

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- Called “Human Factors” by the FDA
- Both in terms of the Essential Requirements (Annex I) and in terms of labeling, the user is now considered a key factor.

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EU Medical Devices Agency

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- **The final proposal does *not* call for the creation of a pan-European devices agency similar to the US FDA.**

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European database

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- Data related to clinical investigations will now be collected for the European databank and shared among Competent Authorities.
- Databank will also include information on registration, certificates and *vigilance* data.
- Data must be submitted in a standardized format, yet to be determined.

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Human tissue

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- Devices that incorporate human tissue, blood or plasma will fall within the scope of Directive 2001/83/EC
- Will be considered Class III.
- Many changes included in this section and companies who have these products should review the draft proposal carefully.

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IVD

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- **IVDs now specifically excluded from Directive 98/8/EC on Biocides, eliminating confusion as to which Directive applies.**

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Outsourced design and mfg

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- If the design or manufacturing of a device is done by a third party, you must demonstrate that you have adequate controls in place to ensure the continued efficient operation of their quality system.

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Notified Bodies

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- Will be required to perform an inspection of design documentation for as representative sample of devices using industry standard statistical techniques and “commensurate” with the risk of the device.

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Post market surveillance

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- Custom devices will now require a post-market surveillance system that is reportable to Competent Authorities.

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Public information

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- Certain non-confidential summary information on devices will now be publicly available.
- Manufacturers of Class IIb and Class III devices will be required to submit a summary of information and data related to the device.

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Record retention

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- **Records must now be maintained for inspection by the Competent Authorities for the "useful life of the product" or 5 years from date of manufacture, whichever is greater.**

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Reusable surgical instruments

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- In earlier drafts, the Commission recommended that these products and other surgically invasive devices for transient use be moved to Class IIa. They will, however, remain Class I devices.

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Software

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- **Will now be considered an active medical device, whether integral with the device or as a standalone product. Software validation will also be an Essential Requirement.**

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More information

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- A highlighted version of the proposed Directive can be found on our website at:

www.emergogroup.com/Resources/Regulations_Europe.asp

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Vigilance and Post Market Surveillance

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A review of the new European guideline MEDDEV 2-12 rev 5

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Quick refresher on Vigilance and Post Market Surveillance in the EU

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PMS System based on information received from:

- Complaints monitoring
- Warranty claims
- Reports from regulatory agencies
- Literature review
- Service/repair

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PMS System based on information received from: (continued)

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- Customer surveys
- Post Market Clinical Follow up
- User feedback other than complaints / sales reps
- Device tracking / implant registration
- User response during training program
- Media
- Experience from similar devices
- In-house testing

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Europe has revised the guideline addressing Vigilance

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- MEDDEV 2-12.1 rev 5 replaces rev 4 issued in 2001
- Clarifies reporting requirements and enacts more stringent timeline requirements
- Discusses content of the European database (EUDAMED)

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Conflicts between old MEDDEV and the CE Directive

- Old MEDDEV says that you needed to report Incidents within 10 or 30 days
- National laws said 2, 5, 10, 15 and 30 days
- All were wrong since MDD says you need to report immediately.
- MEDDEV 2.12 rev 5 fixes this

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Event or Incident...or both?

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- The term “Near Incident” is gone. Now there are only Events” and “Incidents”
- All Incidents are Events, but not all Events are Incidents
- Events may be complaints or something else
- You need to determine whether an “event” is an “incident” quickly

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Timelines

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- Now, if an Event is an Incident, you need to report it immediately
- You do have time to investigate **IF** justified, but…
- This does not mean you can "investigate" every Event. CAs will be watching.
- You have no more than 10 or 30 days to report an EVENT; only 48 hours if a matter of "Public Concern"

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Field safety notices (FSN)

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- Now recommended that you submit a FSN to appropriate CA 48 hours prior to notification to allow comment
- Provides solution to sending it to only one country
- Guideline spells out exact content of the FSN

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Field Safety Corrective Action (FSCA)

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- Recall Notice is now replaced by the Field Safety Corrective Action
- Covers the recall as well
- If recall is ordered **outside** the EU, but product **is** sold in EU, you must issue a FSCA to the CA

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Side Effects

- Old rules exempted “side effects” from reporting
- Some manufacturers created long list of “side effects” so they would not have to report anything
- Side effects now reportable under certain conditions

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EU Device Regulations – Green Dot

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Packaging and Packaging Waste Directive

German Green Dot Program

Licensed to Pro-Europe – other national organizations

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EU Device Regulations – Green Dot

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“Green Dot”

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EU Device Regulations – Green Dot

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Current Membership

28 European Countries

Alliance: UK, The Netherlands, Italy

Other: Canada

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EU Device Regulations – Green Dot

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National Organization are **Non-profit** – pays regional / local waste management companies

Green Dot licenses – applied in each country

License fees determined on the basis of materials, weight and number of units

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EU Device Regulations - WEEE

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Waste Electrical and Electronic Equipment Directive (WEEE)

Into effect August 2005

Aims to reduce electrical and electronic waste through collection, recovery, recycling and treatment of electrical products at the end of their useful life

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EU Device Regulations - WEEE

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Applies to medical equipment

Excluded:

Implants and “infected” devices;

Devices designed for a voltage rating exceeding 1000 Volts AC and 1500 volts DC

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EU Device Regulations - WEEE

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Producer pays principle

Producer prepare data on their device – instructions for recycle and disassembly and locations of dangerous substances

Producer responsible for take back - Two options:

1. **Submit your individual take back plan to the relevant authorities**
2. **Become a member of a collective take back system in each Member State!**

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Labeling Requirement – Wheelie Bin

Disposal Instruction Requirements

EN 50419

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Questions?

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