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Medical Device Regulations: impact and implications

Dr. Gurge Phull

Agenda

- Why
- Changes
- Implications
- Timeline

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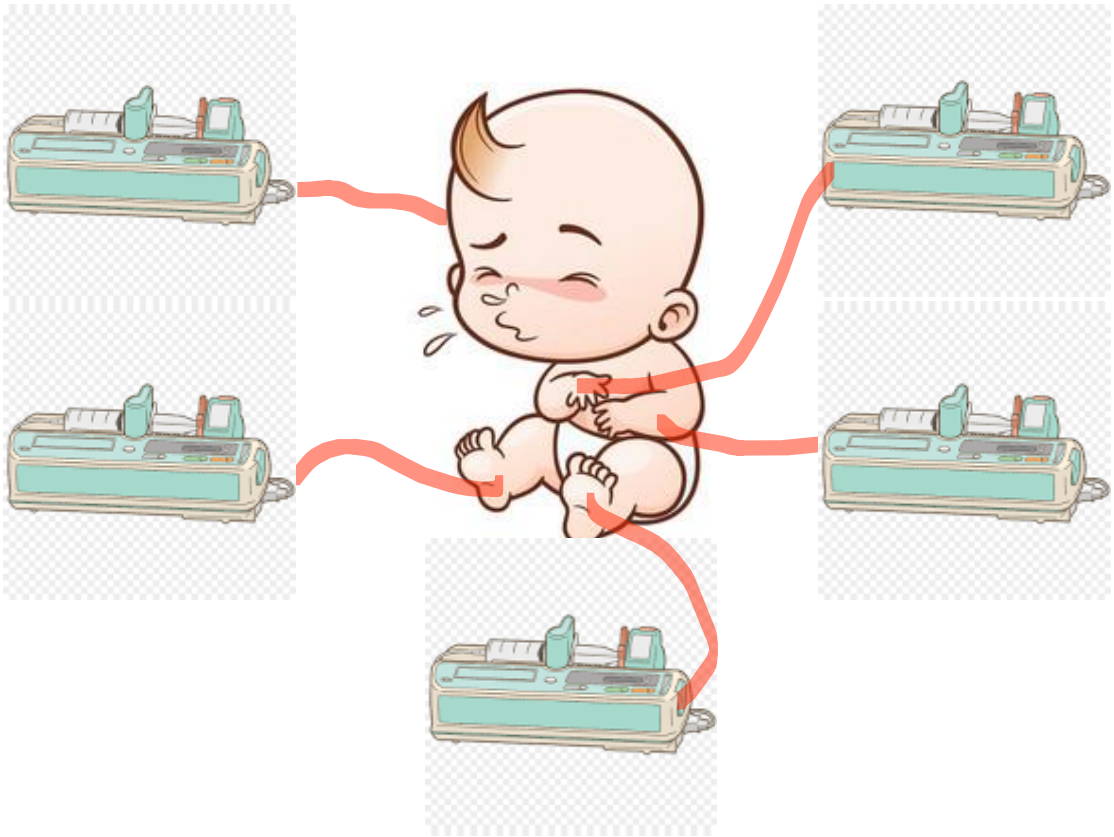
Story



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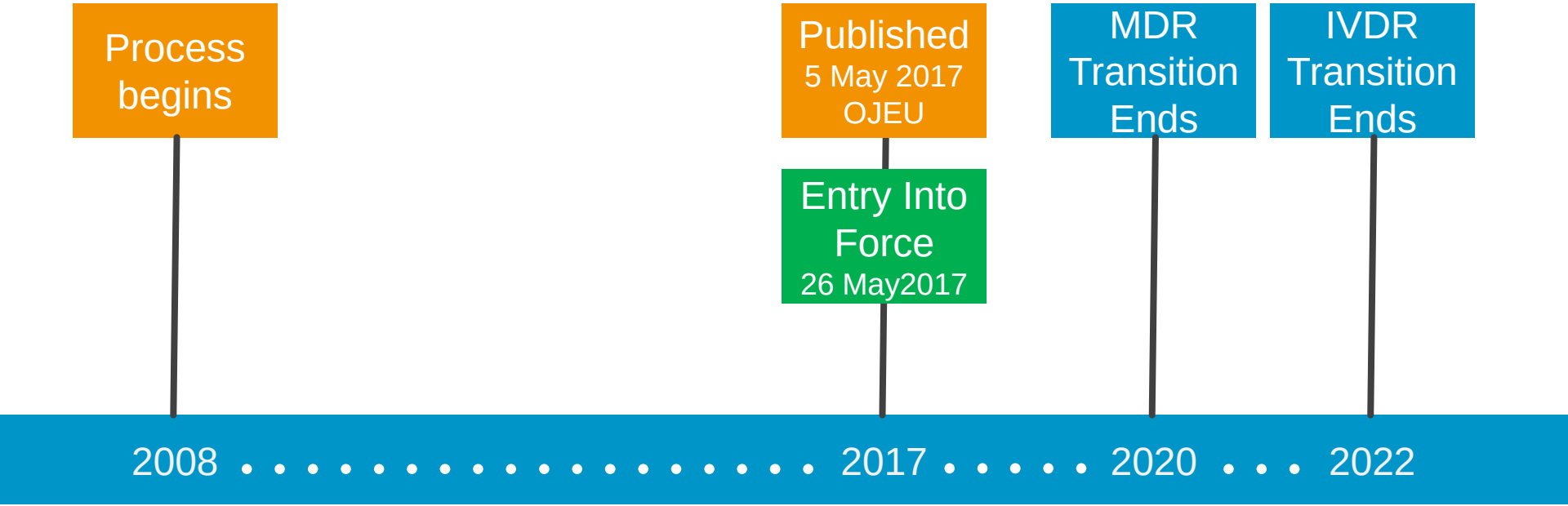
Regulations development



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The path

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Where to find the MDR

Official Journal L 117

of the European Union

English edition — Legislation — Volume 60 — 5 May 2017

Contents

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Directive vs. Regulation

EU DIRECTIVES

Lay down certain end results that must be achieved in each member state however the countries are free to decide how to implement these.

VS.

EU REGULATIONS

Are direct EU law(s), applicable as soon as they are passed and are legally binding in all member states as part of their national law.

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MDD vs. MDR

Medical Devices Directive

60 pages

Active Implantable Directive

35 pages

Medical Devices Regulation

177 pages

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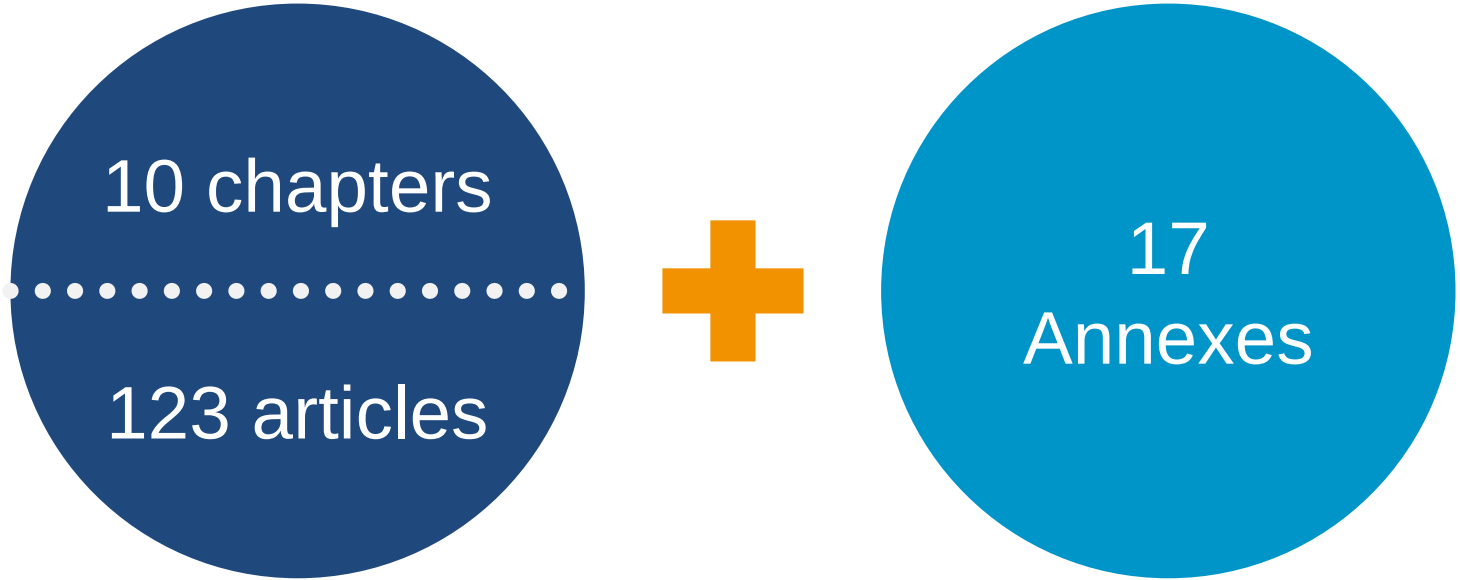
The documents are large and very complex



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What's similar?

- Essential requirements
- Risk Based Classification
- Use of standards
- Third party review

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What's changed?

- Safety & performance requirements
- Additional classification rules
- Clinical evaluation strengthened
- Post market surveillance increased
- Scrutiny
- Transparency

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What does this mean?

More data

Stricter reviews

Vigilance

Surveillance

Transparency
Traceability

Governance

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Annex 1: General Safety & Performance Requirements

- Software (inc. standalone), privacy and security (cyber)
- Devices with a medicine or biological function
- Biological safety / specified chemical carcinogens / hormones etc.
- Label & Information
- Standards / other sources like European pharmacopeia
- Lay people risks
- Cleaning, sterilisation & disinfection (contamination or microbial state)

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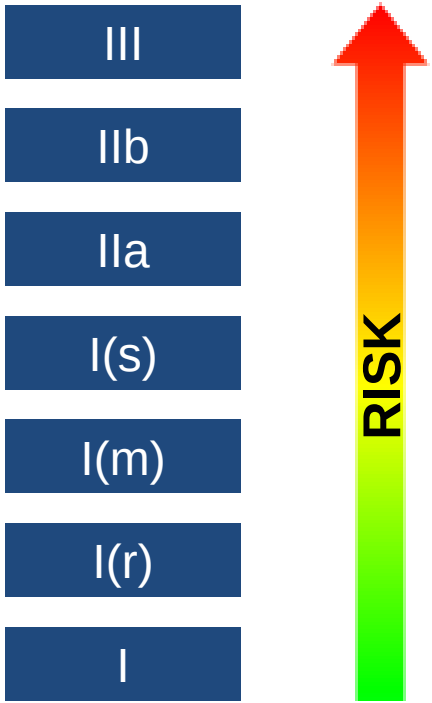
Device - Classes



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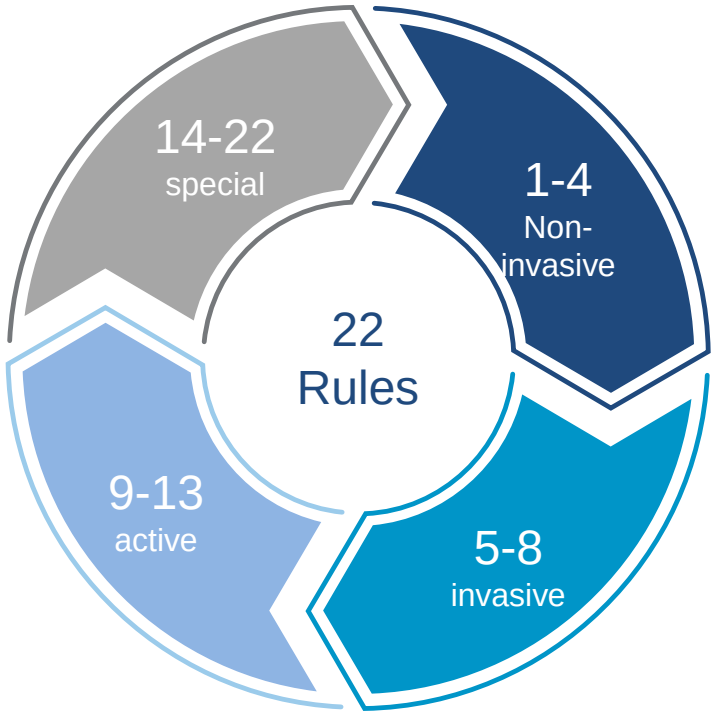
Annex VIII - Classification



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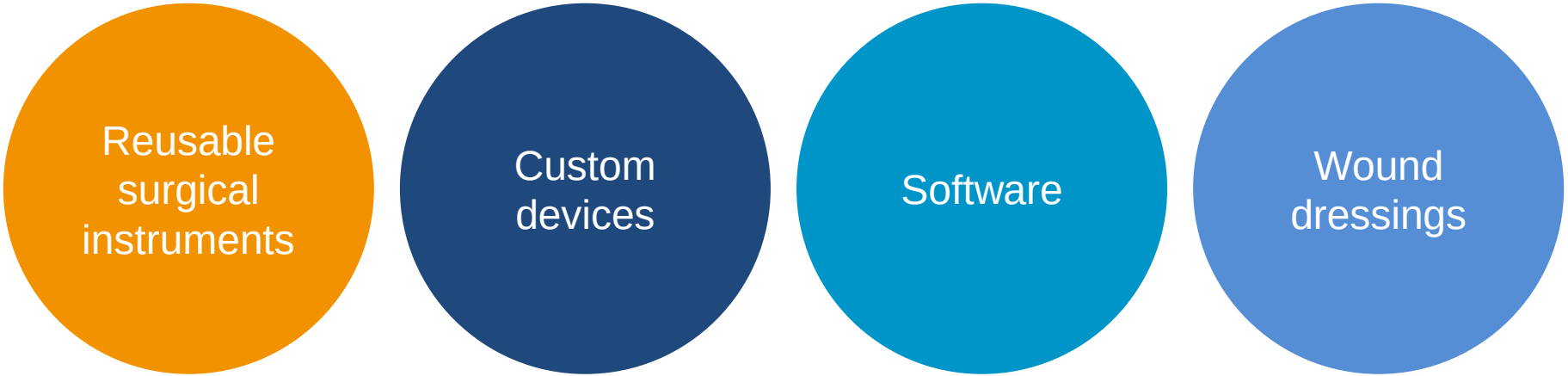
Details - Classes



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Clinical evidence

Report

Evaluation

Data

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Clinical evaluations

- Clinical Evaluation Report (MEDDEV 2.7/1 Rev 4)
- Benefit/Risk evaluation
- Will be scrutinised (data & methodology) by NB & CA
- Increased data requirements
- Data will only be accepted from equivalent device (biology/technical/ clinical)
- Equivalent device(s) need full access to Technical Files and Data
- Many current “equivalent devices” will no longer be accepted

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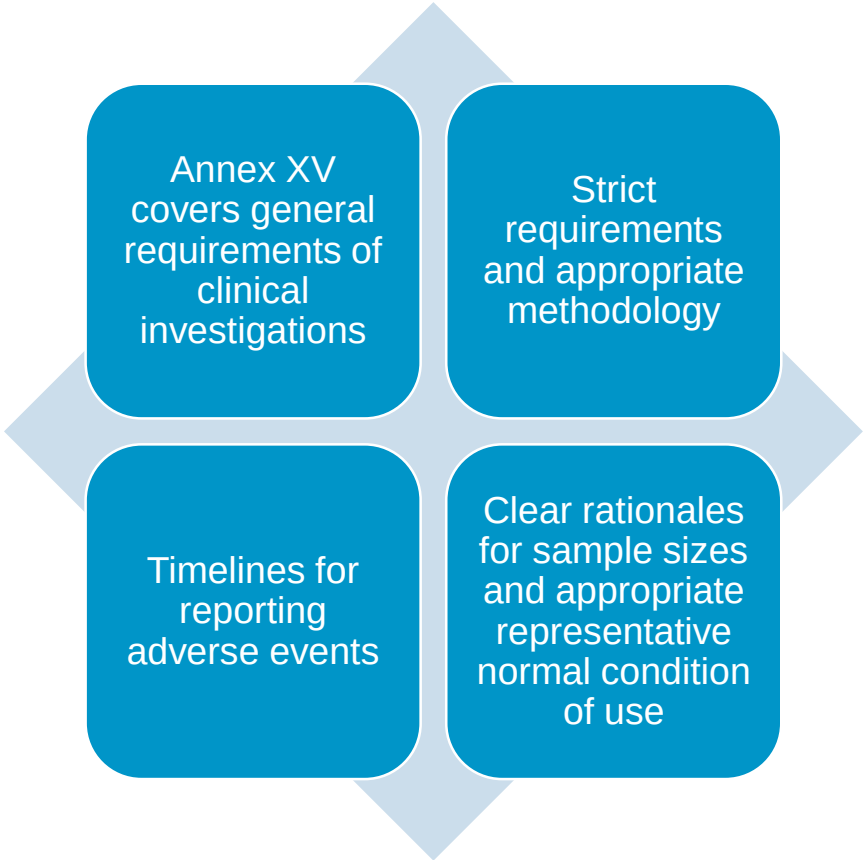
Clinical investigations



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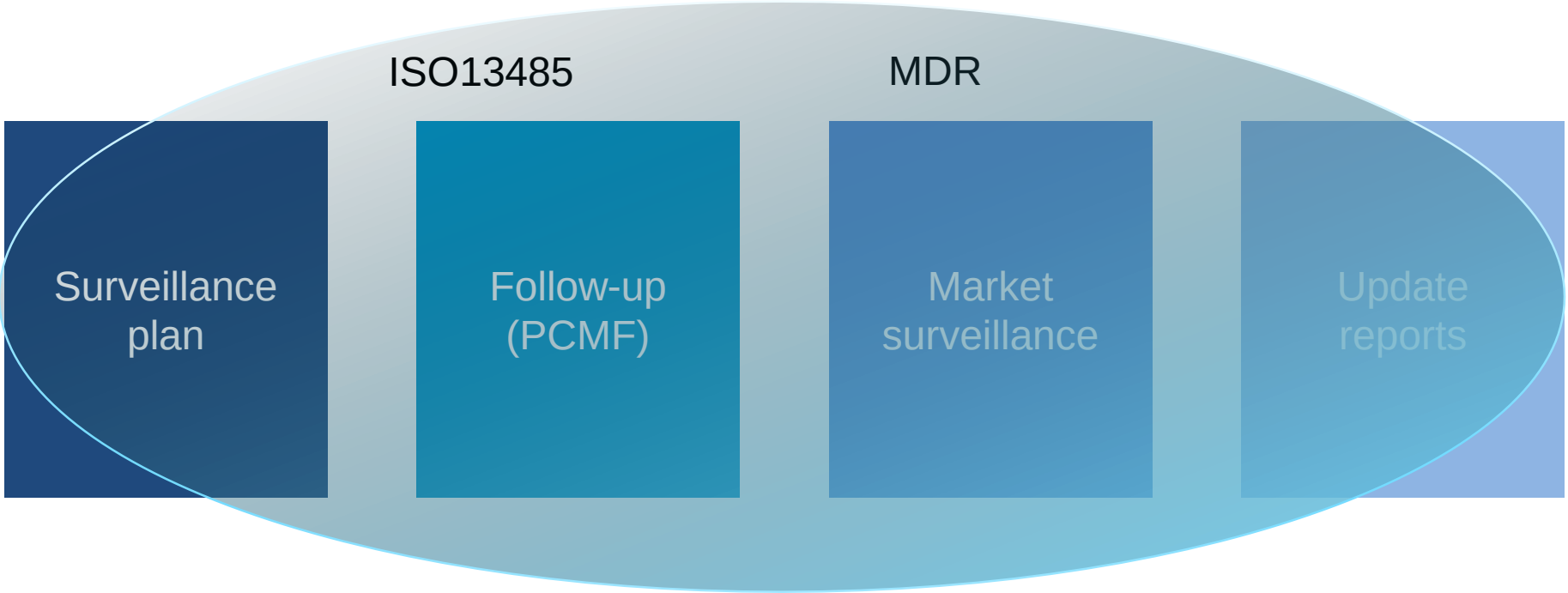
Post-market



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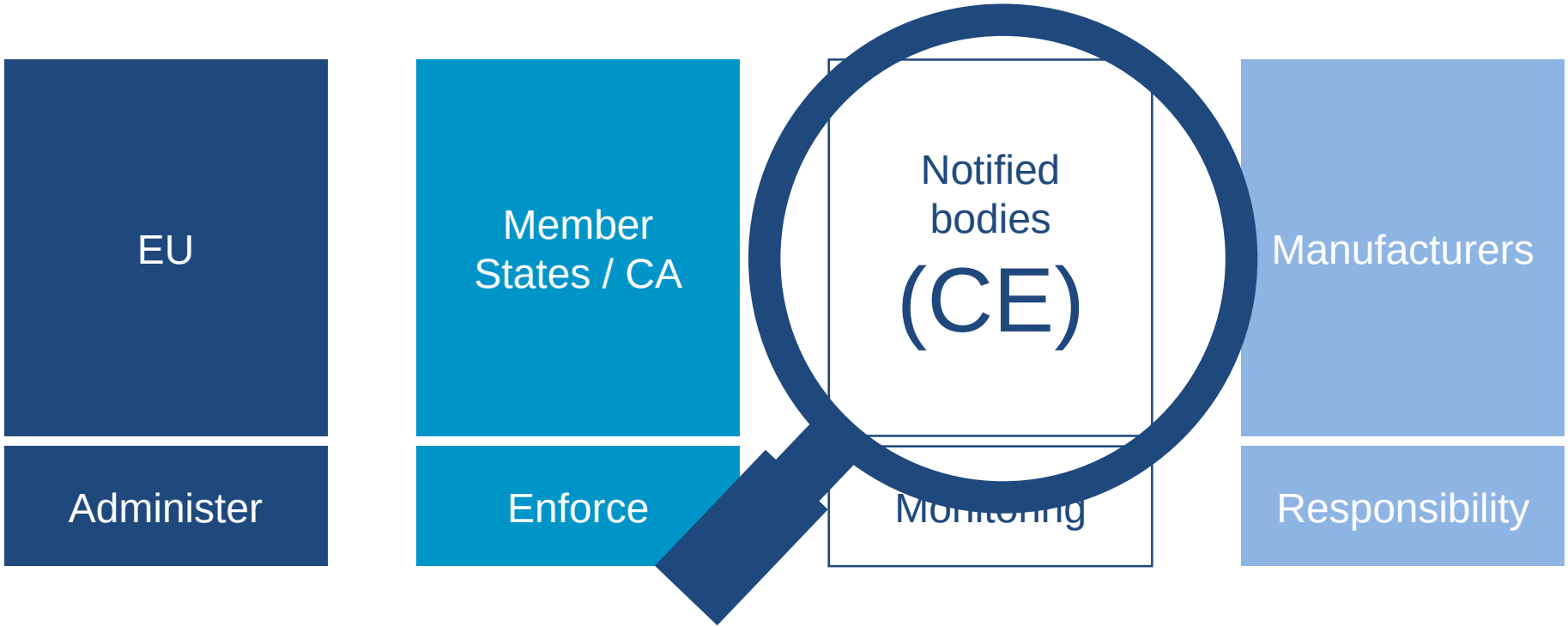
Key Players



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Traceability requirements

Manufacturers information

UDI for each device

Devices, information, clinical investigations, incidents etc.

Update reports

Using EUDAMED

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Obligations of the manufacturer (EUAR / EO)

- Ensure devices are designed and manufactured in accordance with the regulation (MDR/QMS)
- Establish, execute, maintain and document a system for risk management (MDR/QMS/14971)
- Gather clinical evidence, including post-market clinical follow-up (ISO14155 & MEDDEV 2.7/1 Rev 4 & MDR Annexes)
- Prepare and update the technical documentation
- Qualified personnel RA/QA

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Steps to Compliance

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Impact on existing devices

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Impact on existing devices

- No Grandfathering
- Must be State of the Art
- Must have Clinical evidence
- Quality Management System
- Correct Labelling
- RoHS/WEEE/REACH considerations

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Grandfathering?

"A grandfather clause is a provision in which an old rule continues to apply to some existing situations while a new rule will apply to all future cases.

Those exempt from the new rule are said to have grandfather rights or acquired rights, or to have been grandfathered in." - Wikipedia

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State of the Art?

"State of the art means what is currently and generally accepted as good practice" – ISO14971 Annex D.4

Some examples on how to ensure your device is state of the art:

- use of current standards for the same or similar devices
- best practices as used in other devices of the same or similar type
- Results from accepted scientific literature

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Clinical Evidence?

Clinical justifications based on device equivalence to be less accepted

Expected to show:

- Technical
- Biological
- Clinical

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QMS

QMS necessary to achieve compliance

MDR article 10, clause 9

QMS to address at least:

- Risk Management
- Clinical Evaluation
- Product Realisation especially design controls
- Verification of UDI
- Plan, Implementation and maintenance of PMS system
- Communication with stakeholders
- Process of reporting
- Process of monitoring and product improvement

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Refer to TR17223:2018 for Mapping 13485 to MDR article 10

Business Risk & implications

- Risk of having non compliant product
- Compliance planning / timelines
- Reclassification / up-classification of products
- Technical File revisions
- Reduced Notified Body capacity
- Vigilance and Post Market Surveillance
- UDI and registration of products
- Increase resources (budget, training, outsourcing, testing etc.)

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Other considerations

EUDAMED

Common Specifications

BREXIT

Resources

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Transition timeline

- Fewer NB apply for designation (~47)
- Limited will do Class III devices (~1)
- Limited teams perform the designation

- Entire inventory of CE marked devices must be recertified to MDR during this period

NB Designation

MDR applies

MDD

- All Manufacturers must be compliant to MDR - end of Transition Period

2018 2019 2020 2021

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Timelines

26 May 2017	MDR 2017/745
26 November 2017	Notified Bodies designation
26 March 2020	EUDAMED go live date
26 May 2020	MDR date of application
26 May 2022	IVDR date of application
26 May 2024	AIMD, MDD and IVDD certificates become void
26 May 2025	no devices may be put into service in Europe using MDD, AIMD or IVDD certificates

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So … are you ready?

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Questions

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