Medical Devices Regulation
What you need to know

Sophie Tabutin
5th May 2017
First question: What is the difference between a Directive and a Regulation?

- **EU Directive:**
  - Applicable to all Member States
  - Sets certain aims, requirements and concrete results that must be achieved in every Member State
  - Sets a process for it to be implemented by Member States
  - National authorities must create or adapt their legislation to meet these aims by the date specified in each given Directive

- **EU Regulation:**
  - Immediately applicable and enforceable by law in all Member States
  - As good practice, Member States issue national legislation that defines the competent national authorities, inspection and sanctions on the subject matter.
What exactly is changing?

• Medical Devices Directive AND Active Implantable Directive
• In Vitro Diagnostic Directive

• Medical Devices Regulation
• In-Vitro Diagnostic Regulation
MDR/IVDR status update
The EU’s new Medical Devices Regulations

- 2008: EU Commission launches consultation on MD framework
- 2012: EU Commission publishes proposal for new MD Regulation
- 2014 Q2: EU Parliament adopts position on MDR
- 2015 Q3: EU Council adopts position on proposed Regulation
- 2015 Q4: Trilogues between Commission, Parliament and Council starts
- 5 May 2017: Publication of the adopted MDR/IVDR in EUOJ
A little clarity

The meanings of some words

• **Entry into force**
  Publication of the new Regulation in EU Official Journal + 20 Days

• **Date of application (DoA)**
  ‘Transition period’
  3 years after entry into force for MDR
  5 years after entry into force for IVDR
Latest progress

On 25 May 2016 during Trilogue between EU Council, Parliament and Commission, political agreement was reached on new MD and IVD Regulations nearly 8 years after initial negotiations kicked off…

7 Mar 2017: Final adoption by the European Council
5 Apr 2017: Final adoption by European Parliament
5 May: Publication in Official Journal of the European Union (EUOJ)

Texts enter into force 20 days after publication in EUOJ: 25 May 2017
Full application for Medical Devices Regulation: 26 May 2020
Full application for the IVD Regulation: 26 May 2022

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Implementing and Delegated Acts

- Many instances of Delegated Acts and Implementing Acts necessary to make MDR “operational”
- Unclear when these will be available...

E.g:
- Regulatory status of groups of products
- Common Specifications
- Format of Summary of Safety and Performance (SSP)
- UDI
- EUDAMED
- List of NBOG codes
- NB designation procedure

Work in Progress
Regulation (EU) 2017/745

101 Whereas … = Why
10 Chapters of 123 Articles = What
XVII Annexes = How

• Chapter I – Scope and Definitions
• Chapter II – CE Marking, Economic Operators, Reprocessing
• Chapter III – Identification and Traceability of Devices
• Chapter IV – Notified Bodies
• Chapter V – Classification and Conformity Assessment
• Chapter VI – Clinical Evaluation and Investigation
• Chapter VII – Vigilance and Market Surveillance
• Chapter VIII – Cooperation between Member States
• Chapter IX – Confidentiality, Data Protection, Funding, Penalties
• Chapter X – Final Provisions
Regulation (EU) 2017/745

101 Whereas … = Why

10 Chapters of 123 Articles = What

XVII Annexes = How

- Annex I – General safety and performance requirements
- Annex II – Technical Documentation
- Annex III – Technical Documentation on PMS
- Annex IV – EU Declaration of Conformity
- Annex V – CE Marking of Conformity
- Annex VI – European UDI System
- Annex VII – Requirements to be met by Notified Bodies
- Annex VIII – Classification Criteria
- Annex IX – Conformity Assessment – QMS and Technical Documentation
- Annex X – Conformity Assessment – Type Examination
- Annex XI – Conformity Assessment – Product Conformity Verification
- Annex XII – Procedure for Custom-made Devices
- Annex XIII – Certificates issued by a Notified Body
- Annex XIV – Clinical Evaluation and Post-market clinical follow-up
- Annex XV – Clinical Investigations
- Annex XVI – Products without an intended medical purpose
- Annex XVII – Correlation Table 90/385, 93/42 and Regulation
Key changes

**Notified Bodies**
- Strengthened designation criteria
- Joint audits: 3 Member States and Commission (FHAA)
- Unannounced audits

**Clinical evidence**
- Less equivalence, more data for high risk devices
- Publish Safety and Performance data
- Post-market clinical follow-up

**Pre-market**
- Scrutiny for high risk devices
- Common Specifications
- Responsible person for manufacturers and Authorised Representatives
<table>
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<tr>
<th>Category</th>
<th>Details</th>
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| Post-market surveillance and vigilance | • Central database and co-ordination  
• Trend reporting  
• Enforcement activities |
| Transparency and traceability   | • Devices and Economic Operators registered centrally  
• Unique Device Identification (UDI)  
• Implant cards, SSCP |
| Governance and oversight        | • Central Committee: MDCG  
• Expert Panel, Expert Laboratories |
Roles in the regulatory system
2016 – Actors – Who are they?

European Commission, Parliament, Council

Member States
EU, EEA, EFTA, Customs Union, MRA

Notified Bodies

Manufacturer
Suppliers
Subcontractors
EU Authorised Representative
Importer
Distributor

New Legislative Framework
2016 – Actors – What do they do?

Administration
Development comprehensive, coherent and proportionate legislation
Support Member States, ensure co-operation between NBs, harmonised standards, NANDO

National law enforcement
Ensure only safe, compliant products on market
Designate Notified Bodies

Conformity assessment
QMS, product, unannounced
Manufacturer, suppliers, subcontractor

‘… Ultimate responsibility for conformity …’

New Legislative Framework
Market Surveillance
Classification
22 Classification rules:

1 - 4  Non-invasive devices

5 - 8  Invasive devices

9 - 13  Active devices

14 - 22  Special rules
Annex VIII - Classification

Some new rules, new definitions, some clarifications, some upclassifications…

**Rule 3:** Upclassification of IVF media/solutions for organ storage to Class III

**Rule 8:** Upclassification of surgical meshes and spinal devices to Class III

**Rule 9:** Active devices intended for controlling, monitoring or directly influencing the performance of active implantable devices are Class III

**Rule 11:** Upclassification of some softwares (decision making SW, monitoring of physiological parameters) from Class I to IIa

...
Annex VIII – new rules

**Rule 19:** Nanomaterials – Class IIa/IIb/III

**Rule 20:** Invasive devices with respect to body orifices, [...] intended to administer medicinal products by inhalation are classified as Class IIa, unless their mode of action has an essential impact on the efficacy and safety of the administered medicinal product or they are intended to treat life-threatening conditions, in which case they are classified as Class IIb.

**Rule 21:** Devices that are composed of substances or combinations of substances that are intended to be introduced into the human body via a body orifice, or applied on skin and that are absorbed by or locally dispersed in the human body – Class IIa/IIb/III

**Rule 22:** Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as Class III - Upclassification from Class IIb to Class III.
Article 1 – Scope – Annex XVI – No medical purpose

- **Contact lenses** or other articles intended to be introduced into or onto the eye;
- Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts, with the exception of tattooing products and piercings;
- Substances, combinations of substances, or articles intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing;
- **Equipment** intended to be used to reduce, remove, or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty;
- High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment;
- **Equipment** intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.
Clinical
A few Slides
Clinical evidence

- The **clinical data** and **clinical evaluation report** pertaining to a device
- **Sufficient amount and quality** to allow a qualified assessment of whether the device achieves the intended clinical benefit(s) and safety, when used as intended by the manufacturer

Clinical evaluation

- A methodologically sound / systematic and planned process to continuously generate, collect, analyse and assess the **clinical data** pertaining to a device
- To verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer

Clinical data

- Clinical investigation on the device concerned
- Clinical investigation reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated
- **Peer reviewed** scientific literature on other clinical experience of either the device in question or a similar device for which equivalence can be demonstrated
- Data from the manufacturer’s post-market surveillance system, in particular post-market clinical follow-up
Technical
- Be of similar design
- Used under similar conditions of use
- Have similar specifications and properties (e.g. physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength, software algorithms, porosity, particle size, nanotechnology, specific mass, atomic inclusions – nitrocarburising, oxidability)
- Use similar deployment methods (if relevant)
- Have similar principles of operation and critical performance requirements

Biological
- Use same materials or substances in contact with the same human tissues or body fluids
- For a similar kind and duration of contact and similar release characteristics of substances
- Including degradation products and leachables
- Exceptions can be foreseen for devices in contact with intact skin and minor components; in these cases risk analysis results may allow the use of similar materials taking into account the role and nature of the similar material. Evaluators should consider biological safety (e.g. ISO 10993) as well as other aspects necessary for a comprehensive demonstration of equivalence. A justification explaining the situation should be provided for any difference.

Clinical
- Used for the same clinical condition or intended purpose (including similar severity and stage of disease, medical indication)
- At the same site in the body
- In a similar population (including age, gender, anatomy, physiology)
- Have same kind of user
- Not foreseen to deliver significantly different performances
- Have similar relevant critical performance according to the expected clinical effect for a specific intended purpose
In the case of implantable devices and devices falling within class III, clinical investigations shall be performed except if:

- the device has been designed by modifications of a device already marketed by the same manufacturer
- the modified device has been demonstrated to be equivalent and this has been endorsed by the Notified Body (Annex XIV)

and

- the clinical evaluation is sufficient to demonstrate conformity with the relevant safety and performance requirements.

In this case the notified body shall check that the PMCF plan is appropriate and includes post market studies to demonstrate the safety and performance of the device.

Clinical investigations need not be performed in the following cases - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors for which the clinical evaluation is based on sufficient clinical data and is in compliance with the relevant product-specific common specification, where such a common specification is available

... in view of similar well-established technologies - Delegated Act - add or remove to this list ...
Chapter III – Identification and traceability of devices – Article 33 – European Databank

**Electronic System on Registration**
- Conformity Assessment
  - (Applications + Summary of Safety and Clinical Performance)

**Electronic System on Certificates**
- (issued, reissued, refused, suspended, withdrawn)

**Electronic System on Vigilance**
- (incidents, FSCA, FSN + PSUR?)

**Electronic System on Market Surveillance**
- (measures taken by Member States)

**Electronic System on Clinical Investigations**
- (sponsors, description of investigational device, comparators, purpose, status)

**Electronic System on UDI**

**Electronic System on Registration - Manufacturers & Authorised Representatives - SRN**
Post market
True or False?

Existing devices will be automatically grandfathered into the new Regulation without need for clinical investigation or further documentation.

☐ True  ☑ False
Applies to every class of device under every route of conformity.
Post-market surveillance, vigilance and market surveillance - Article 86 – Periodic Safety Update Report

- Per device and where relevant per category or group of devices, manufacturers of devices in Class IIa, IIb and III shall prepare a periodic safety update report summarising the results and conclusions of the analyses of the gathered post-market surveillance data referred to in article 84 together with a rationale and description of any preventive and corrective actions taken.

- Manufacturers of Class IIb and III devices shall update the report at least annually.

- Manufacturers of Class IIa devices shall update the report when necessary and at least every two years.

- Manufacturers of devices in Class III or implantable devices shall submit reports by means of the electronic system to the notified body. The notified body shall review the report and add its evaluation to the database with details of any action taken. Such reports and the notified body evaluation shall be available to competent authorities through the electronic system.

Throughout lifetime:

- Conclusions of the benefit risk determination
- Main findings of PMCF
- Volume of sales
- Estimate of the population that use the device
- Where practicable usage frequency of the device
Identification and traceability of devices
- Article 32 - Summary of Safety and Clinical Performance

• In the case of devices classified as Class III and implantable devices, the manufacturer shall draw up a summary of safety and clinical performance.

• It shall be written in a way that is clear to the intended user and, if relevant, to the patient and shall be available to the public via EUDAMED.

• The draft of this summary shall be submitted to the notified body and shall be validated by that body. After validation the notified body shall upload this summary report to Eudamed. The manufacturer shall mention on the label or instructions for use where the summary report is available.

Article 61 - Clinical Evaluation

For Class III devices and implantable devices, the PMCF evaluation report and, if indicated, the Summary of Safety and Clinical Performance shall be updated at least annually with such data.

• Manufacturer + SRN
• Device + UDI
• Intended purpose, indications, contraindications
• Description, previous variant(s), differences, accessories, other products intended to be used in combination
• Possible diagnostic or therapeutic alternatives
• Harmonised Standards / Common Specifications
• Summary of the Clinical Evaluation Report + PMCF
• Suggested profile and training for users
• Information on residual risks, undesirable effects, warnings & precautions

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Transition period
Article 120
Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC prior to 25 May 2017 shall remain valid until the end of the period indicated on the certificate.

Certificates under 90/385/EEC and 93/42/EEC before MDR Adoption: 5yrs

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<th>Year -1</th>
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Entry into Force 25 May 2017

Date of Application 26 May 2020
Article 120 – Transitional provisions Paragraph 2 - 1


*Batch Verification Certificates before MDR Adoption: 2yrs after Application

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Entry into Force
25 May 2017

Date of Application
26 May 2020

* Batch verification certificates have no expiry date

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Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC from 25 May 2017 shall remain valid until the end of the period indicated on the certificate, which shall not exceed five years from its issuance. They shall however become void at the latest on 27 May 2024.

MDD/AIMD Certificates after MDR Adoption: Full 5yrs

MDD/AIMD Certificates issued after 27 May 2019 expire 26 May 2024

Entry into Force 25 May 2017
Date of Application 26 May 2020

27 May 2024
By way of derogation from Article 5 of this Regulation, a device with a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and which is valid by virtue of paragraph 2 of this Article may only be placed on the market or put into service provided that from the date of application of this Regulation it continues to comply with either of those Directives, and provided there are no significant changes in the design and intended purpose. However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives.

Entry into Force
25 May 2017

Date of Application
26 May 2020

MDD/AIMD Certificates after MDR Adoption: Full 5yrs

MDD/AIMD Certificates issued after 27 May 2019 expire 26 May 2024

If no significant change to design/ intended use

post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices

27 May 2024
Devices lawfully placed on the market pursuant to Directives 90/385/EEC and 93/42/EEC prior to 26 May 2020, and devices placed on the market from 26 May 2020 by virtue of a certificate as referred to in paragraph 2 of this Article, may continue to be made available on the market or put into service until 27 May 2025.
Article 120 – Transitional provisions Paragraphs 5 & 6

• By way of derogation from Directives 90/385/EEC and 93/42/EEC, devices which comply with this Regulation may be placed on the market prior to 26 May 2020.

• By way of derogation from Directives 90/385/EEC and 93/42/EEC, conformity assessment bodies which comply with this Regulation may be designated and notified prior to 26 May 2020. Notified bodies which are designated and notified in accordance with this Regulation may carry out the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation prior to 26 May 2020.
Transition timelines MDR (Article 120)

25 May 2017
Entry into Force

26 May 2020
Date of Application

27 May 2024

MDD/AIMD « grace period »
4 years

27 May 2022

Annex IV/6 certificates void

No more « placing on the market » of devices covered by MDD/AIMD certificates

27 May 2025

MDD/AIMD certificates

MDR certificates

Transition period
3 years

NB designation under MDR

all MDD/AIMD certificates void

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Transition timelines MDR (Article 120)

- **25 May 2017** Entry into Force
- **26 May 2020** Date of Application
  - **MDD/ AI MD « grace period » 4 years**
    - 27 May 2022
  - **Annex IV/ 6 certificates void**
- **27 May 2024**
  - **Only if no significant changes in design and intended purpose.**
  - **No more « placing on the market » of devices covered by MDD/ AI MD certificates**
- **27 May 2025**
  - **all MDD/ AI MD certificates void**

**NB designation under MDR**

**PMS, market surveillance, vigilance, registration of economic operators and of devices according to MDR**

**MDR certificates**

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MDR transition (Article 120)

- **Date of Application**: May 2020
- **Transition period**: 3 years
- **MDD/AI MD certificate validity**: 4 years
- **MDR certificates**
- **PMS, market surveillance, vigilance, registration of economic operators and of devices according to MDR**
- **NBs designation under MDR**

Only if no significant changes in design or intended purpose.
EU MDR – Designation – Article 38, 39 & 40
Where can I find full details of the changes?

bsigroup.com/MDR-revision
bsigroup.com/IVDR-revision

Webinars: bsigroup.com/webinars
Whitepapers: bsigroup.com/whitepapers

Please ask if you want any extra information from BSI.