Medical Devices Regulation
What you need to know

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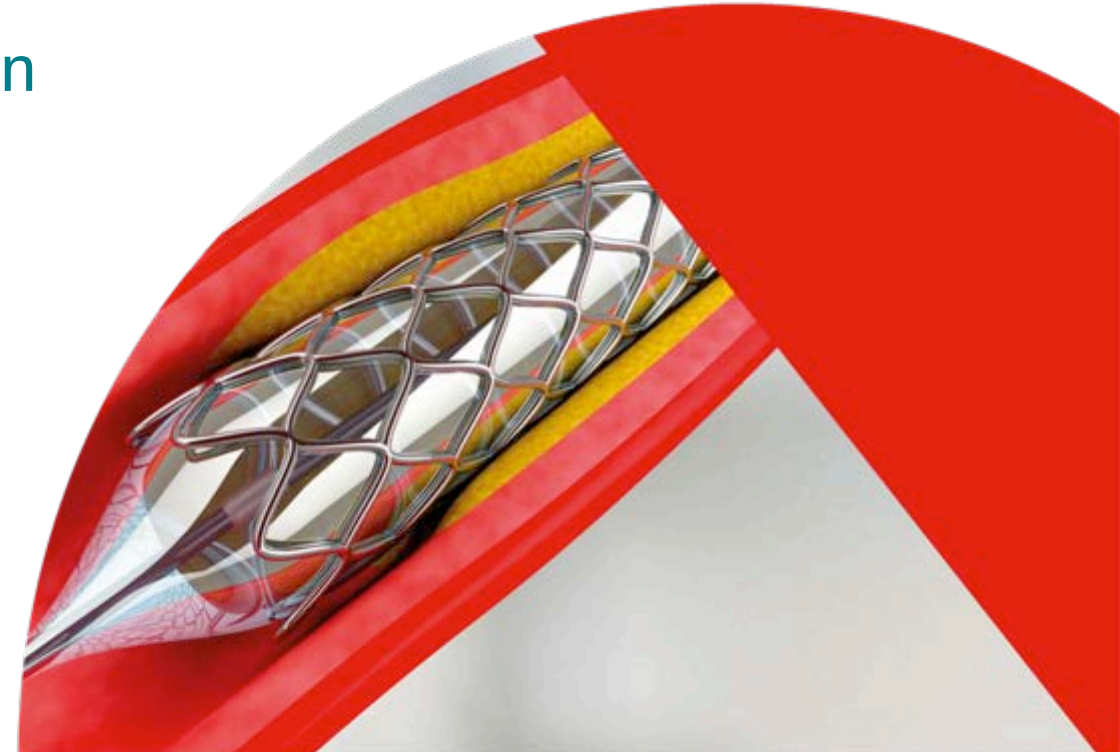
5th May 2017



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.

EU Directives lay down certain end results that must be achieved in every Member State. National authorities have to adapt their laws to meet these goals, but are free to decide how to do so. **Regulations** are the most direct form of EU law - as soon as they are passed, they have binding legal force throughout every Member State, on a par with national laws. National governments do not take action themselves to implement EU regulations, but do ensure their national law does not define the subject matter any further.

What exactly is changing?

- Medical Devices Directive AND Active Implantable Directive

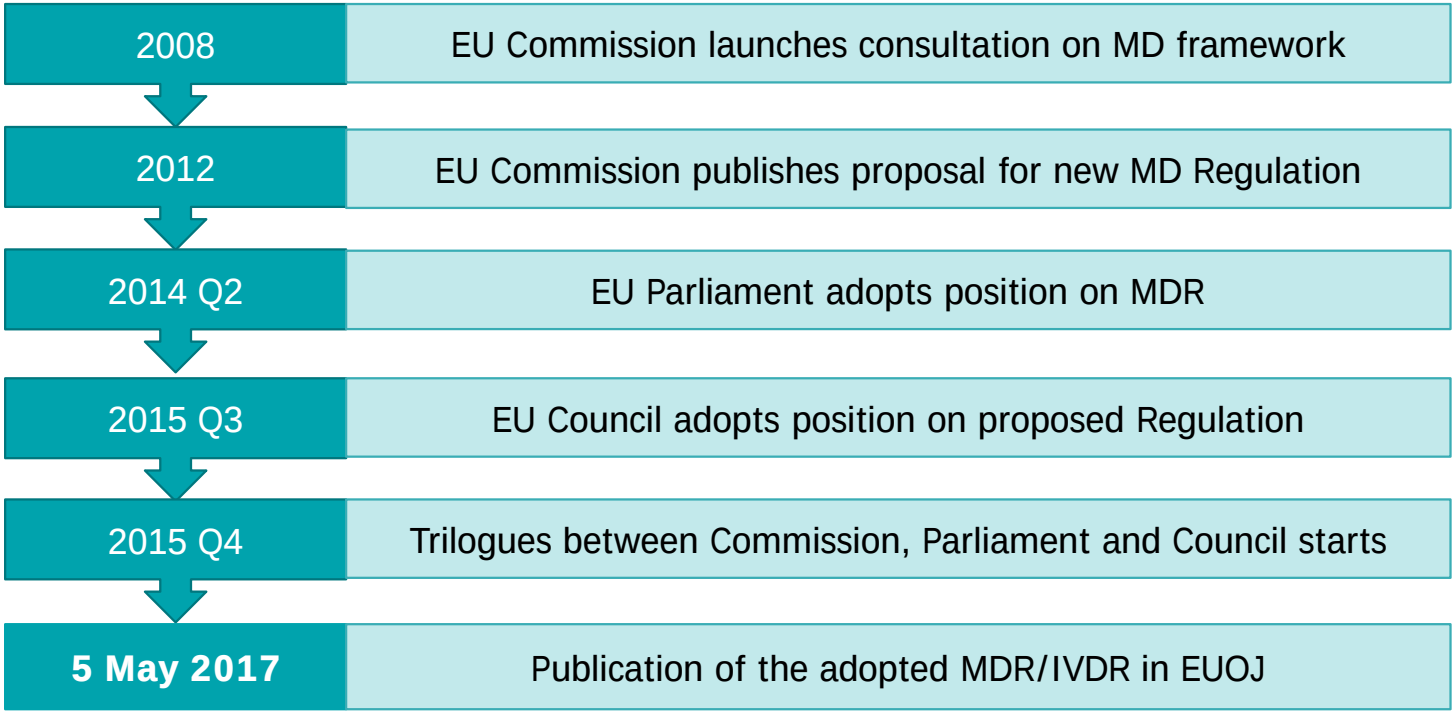
- Medical Devices Regulation

- In Vitro Diagnostic Directive

- In-Vitro Diagnostic Regulation

MDR/IVDR status update

The EU's new Medical Devices Regulations



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 Councile, 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**

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

...

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

Key changes

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?

Blue Guide 2016/C 272/01

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 CE

2016 – Actors – What do they do? Blue Guide 2016/C 272/01

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

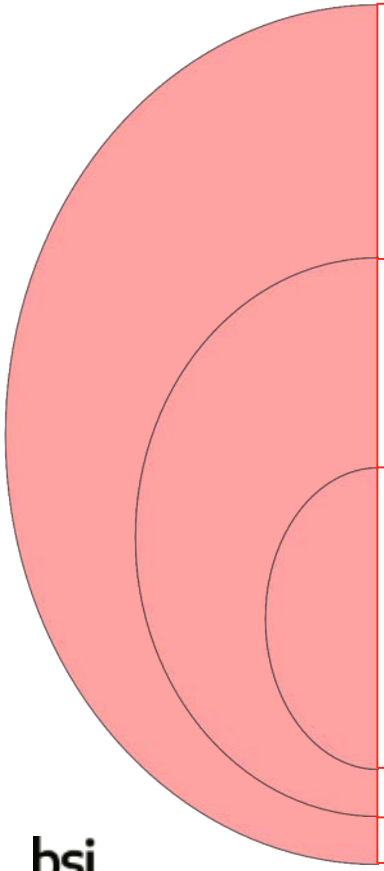
Article 1 – Scope – Annex XVI – No medical purpose

- 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 – MedDev 2.7.1 & MDR



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

MedDev 2.7.1 Rev 3 / MedDev 2.7.1 Rev 4 / MDR – Equivalence

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

MDR – Clinical evaluation and investigation – Article 61 – Clinical evaluation

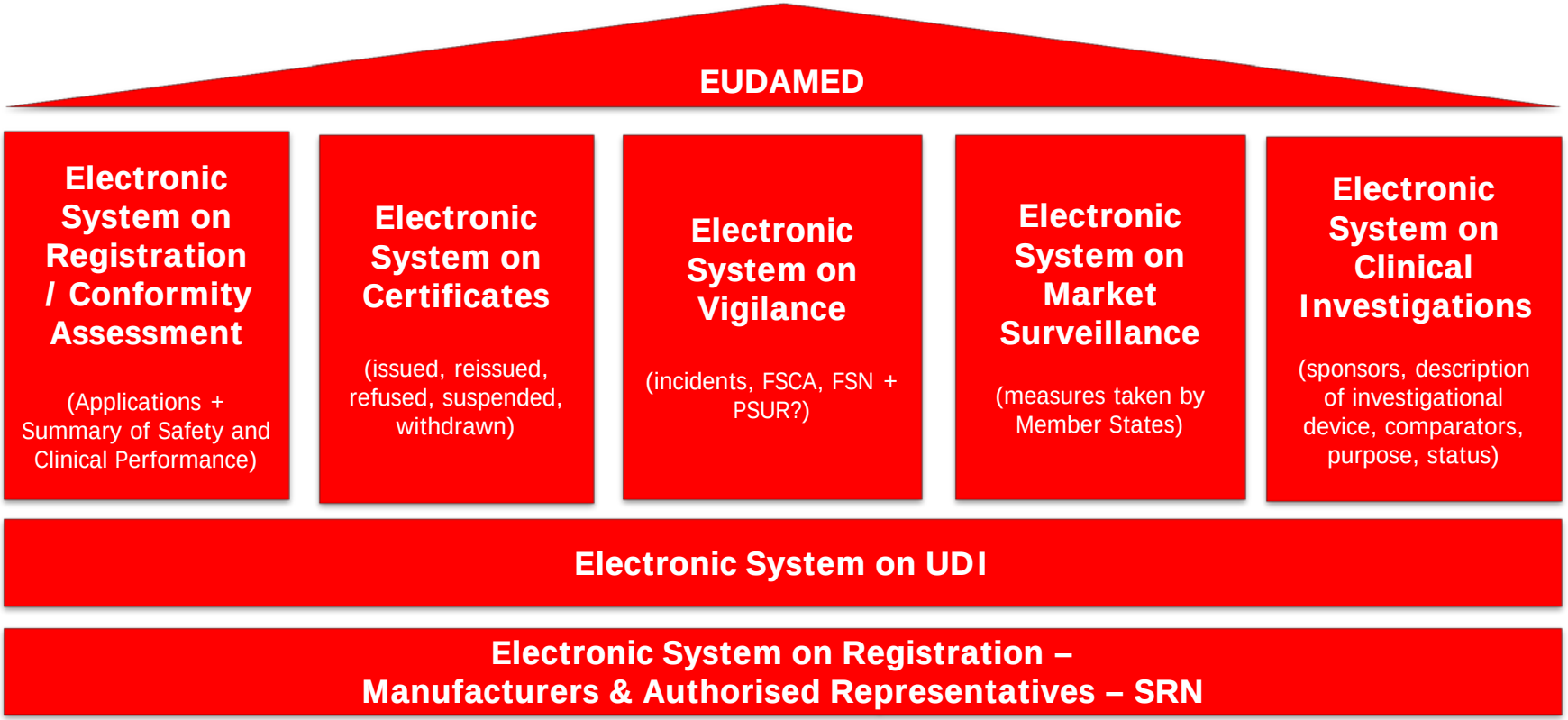
- In the case of implantable devices **and** devices falling within class III, clinical investigations shall be performed except if:
  - the device has been designed by modifications of a device already marketed by the **same manufacturer**
  - the modified device has been demonstrated to be equivalent 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



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**

QMS

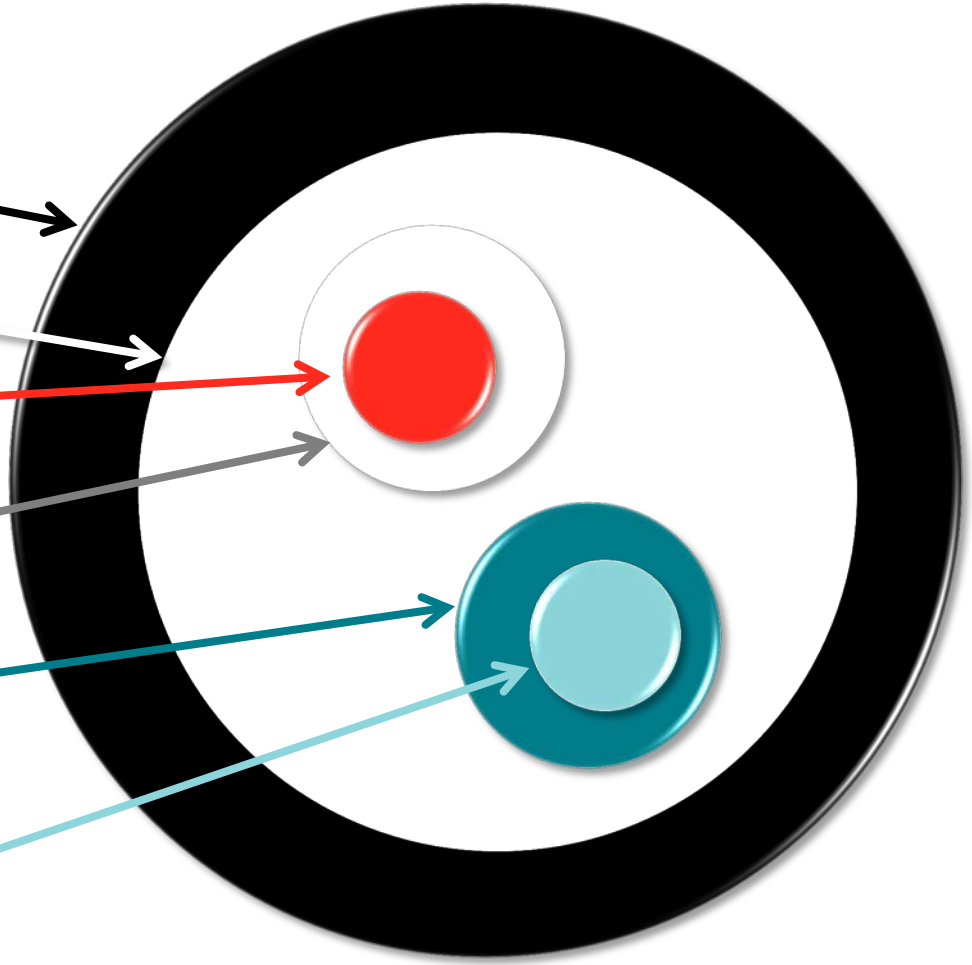
PMS
Article 60a

Vigilance
Article 61-66

Reactive PMS

Proactive PMS

Post Market Clinical Follow-up
Annex XIII



bsi.

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.

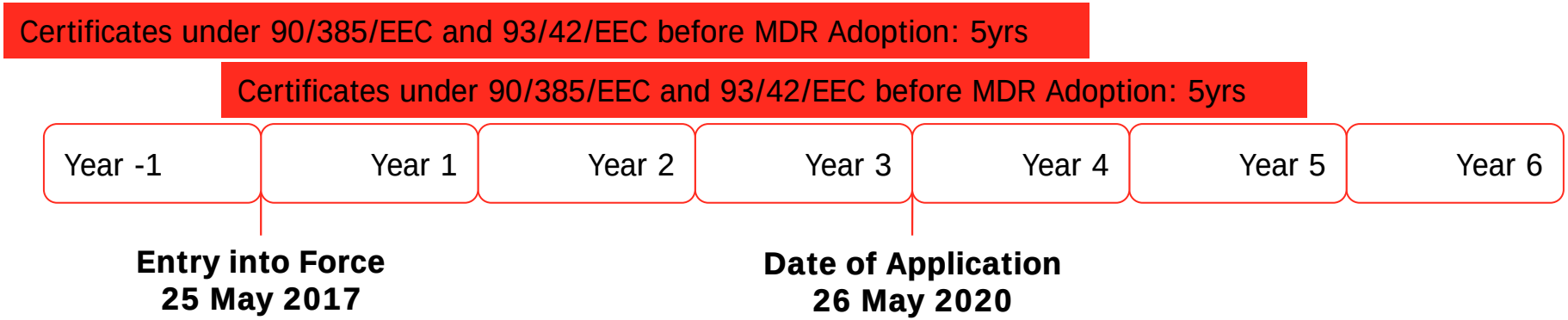
- Manufacturer + SRN
- Device + UDI
- Intended purpose, indications, contra-indications
- Description, previous variant(s), differences, accessories, other products intended to be used in combination
- Possible diagnostic or therapeutic alternatives
- Harmonised Standards / Common Specifications
- Summary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

Transition period

Article 120

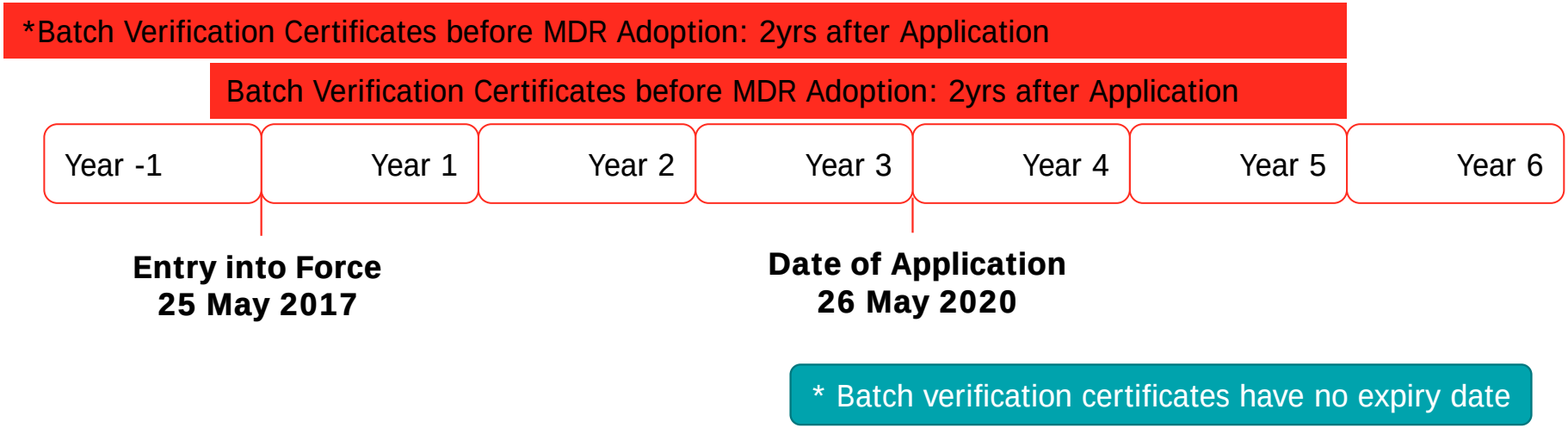
Article 120 – Transitional provisions Paragraph 2 - 1

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



Article 120 – Transitional provisions Paragraph 2 - 1

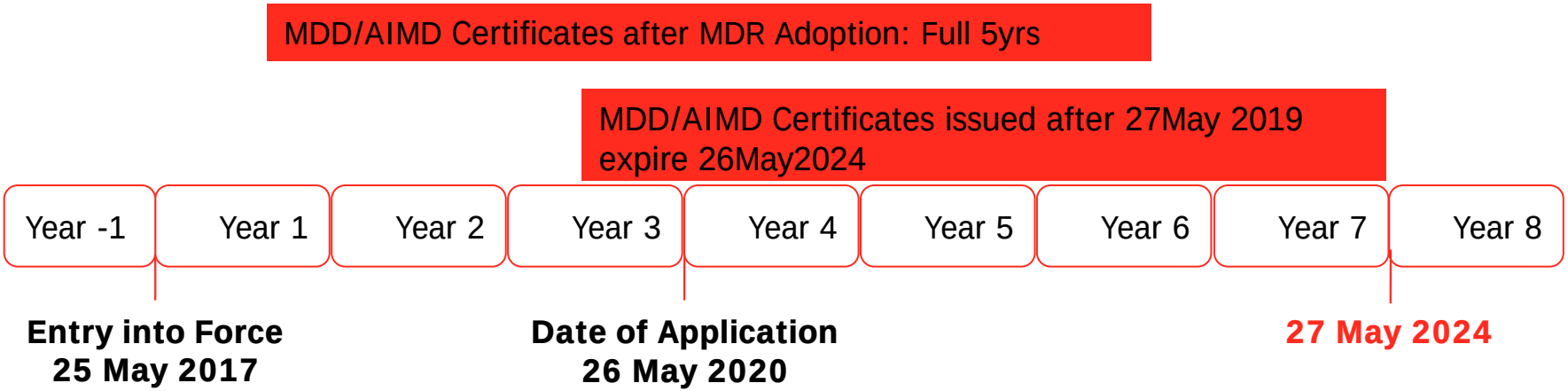
Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC prior to 25 May 2017 shall remain valid until the end of the period indicated on the certificate, except for **certificates** issued in accordance with **Annex 4 of Directive 90/385/EEC** or **Annex IV of Directive 93/42/EEC** which shall become void at the latest on **27 May 2022.**



* Batch verification certificates have no expiry date

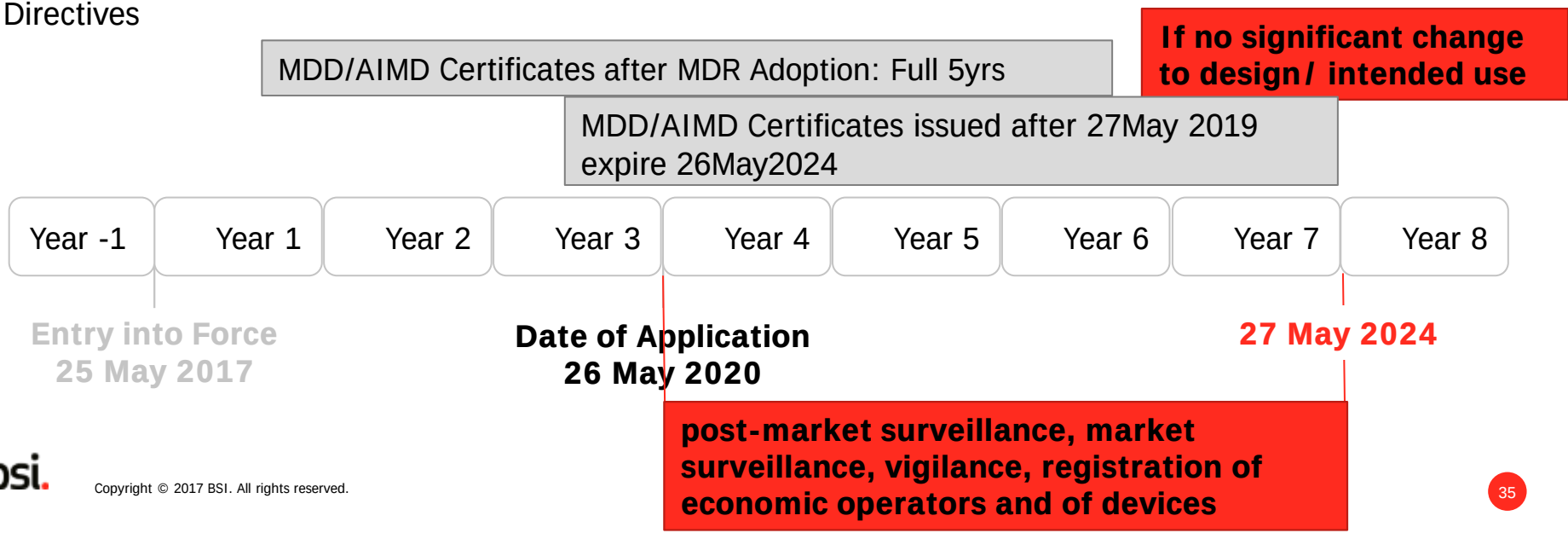
Article 120 – Transitional provisions Paragraph 2 - 2

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**



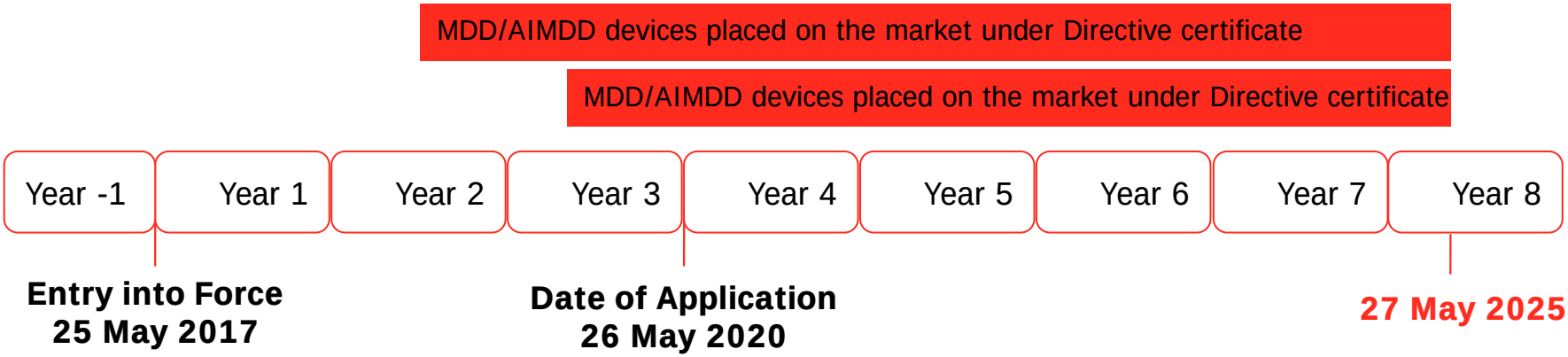
Article 120 – Transitional provisions Paragraph 3

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



Article 120 – Transitional provisions Paragraph 4

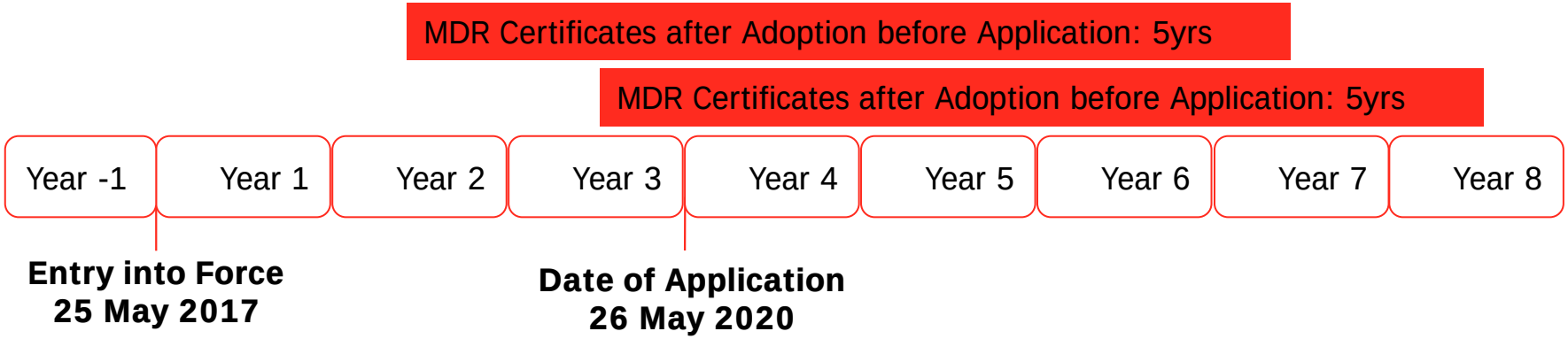
Devices lawfully **placed on the market** pursuant to Directives 90/385/EEC and 93/42/EEC prior to **26 May 2020**, and devices placed on the market from **26 May 2020** by virtue of a certificate as referred to in paragraph 2 of this Article, may continue to be made available on the market or put into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



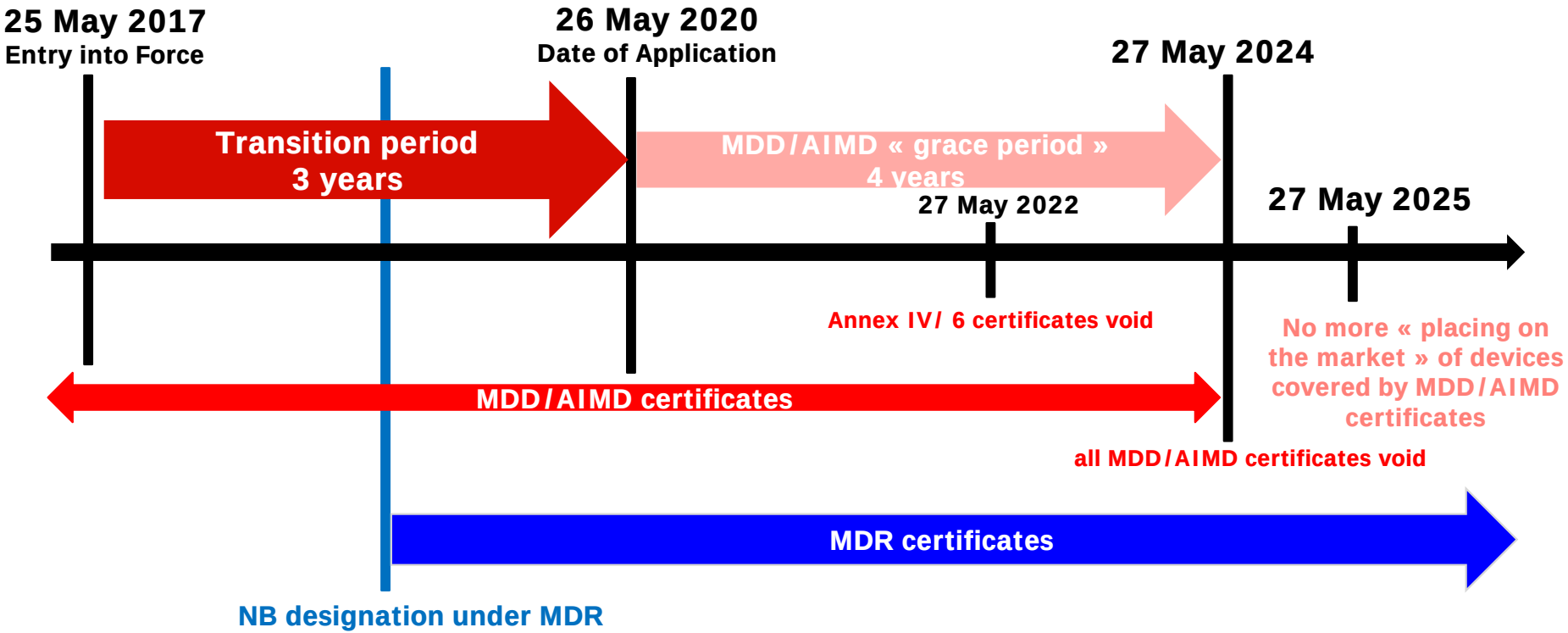
Article 120 – Transitional provisions Paragraphs 5 & 6

- 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**.

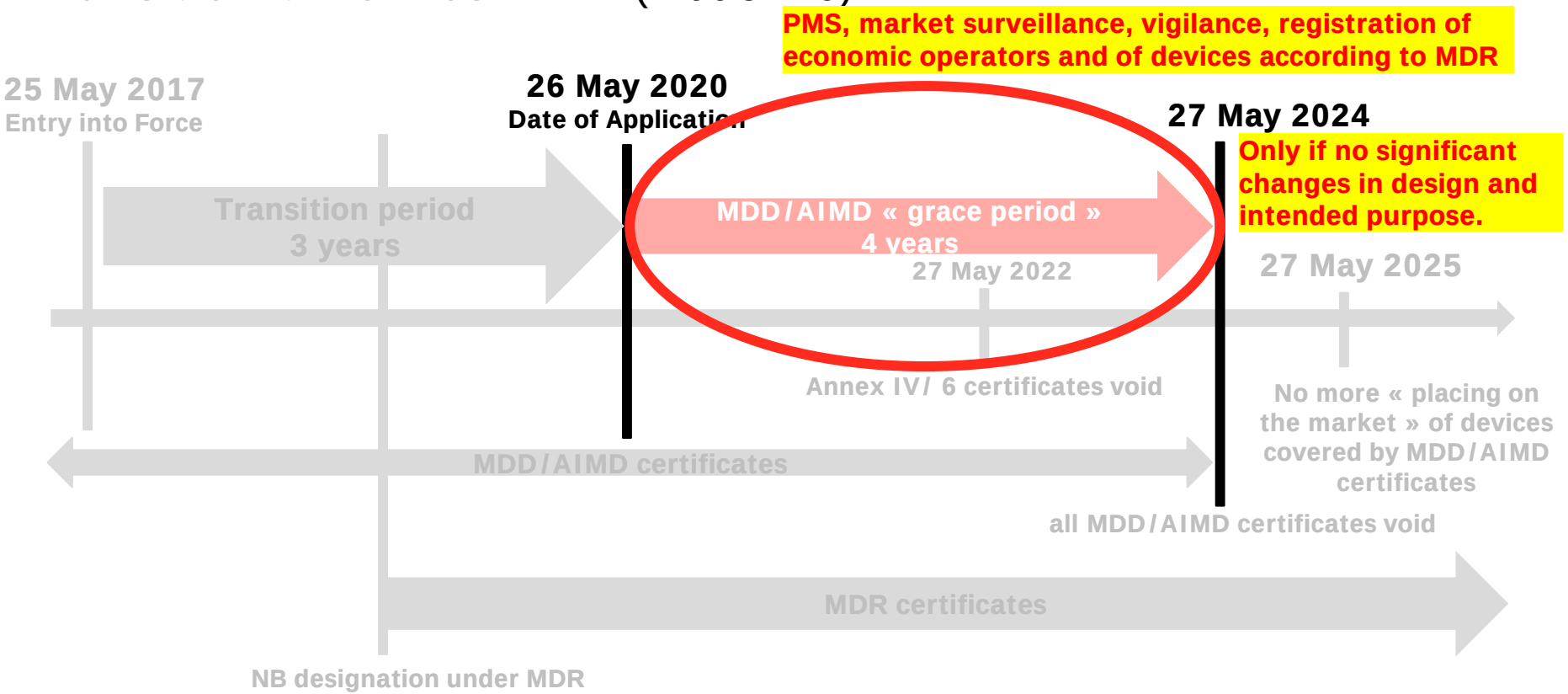
- By way of derogation from Directives 90/385/EEC and 93/42/EEC, conformity assessment bodies which comply with this Regulation may be designated and notified prior to **26 May 2020**. Notified bodies which are designated and notified in accordance with this Regulation may carry out the conformity assessment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



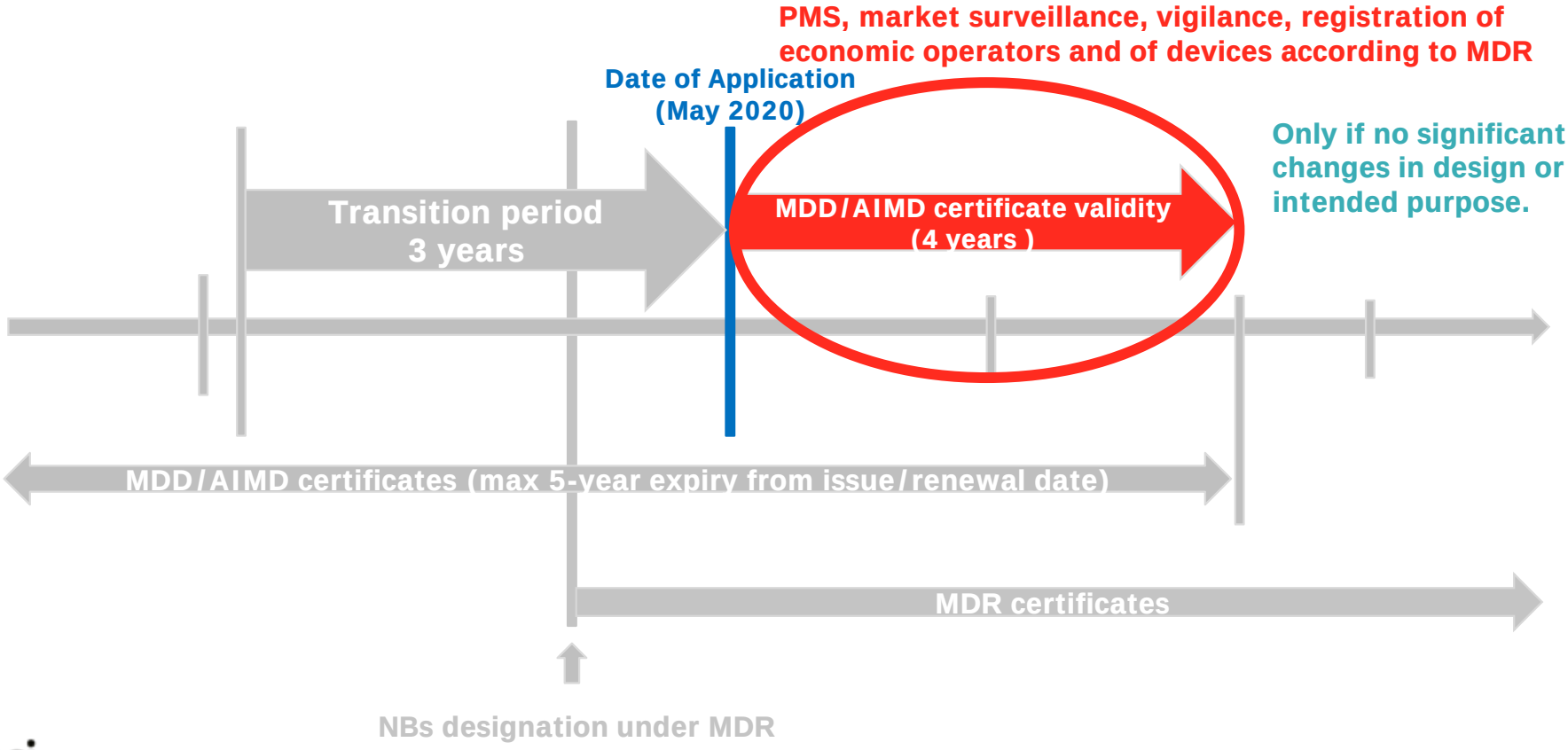
Transition timelines MDR (Article 120)



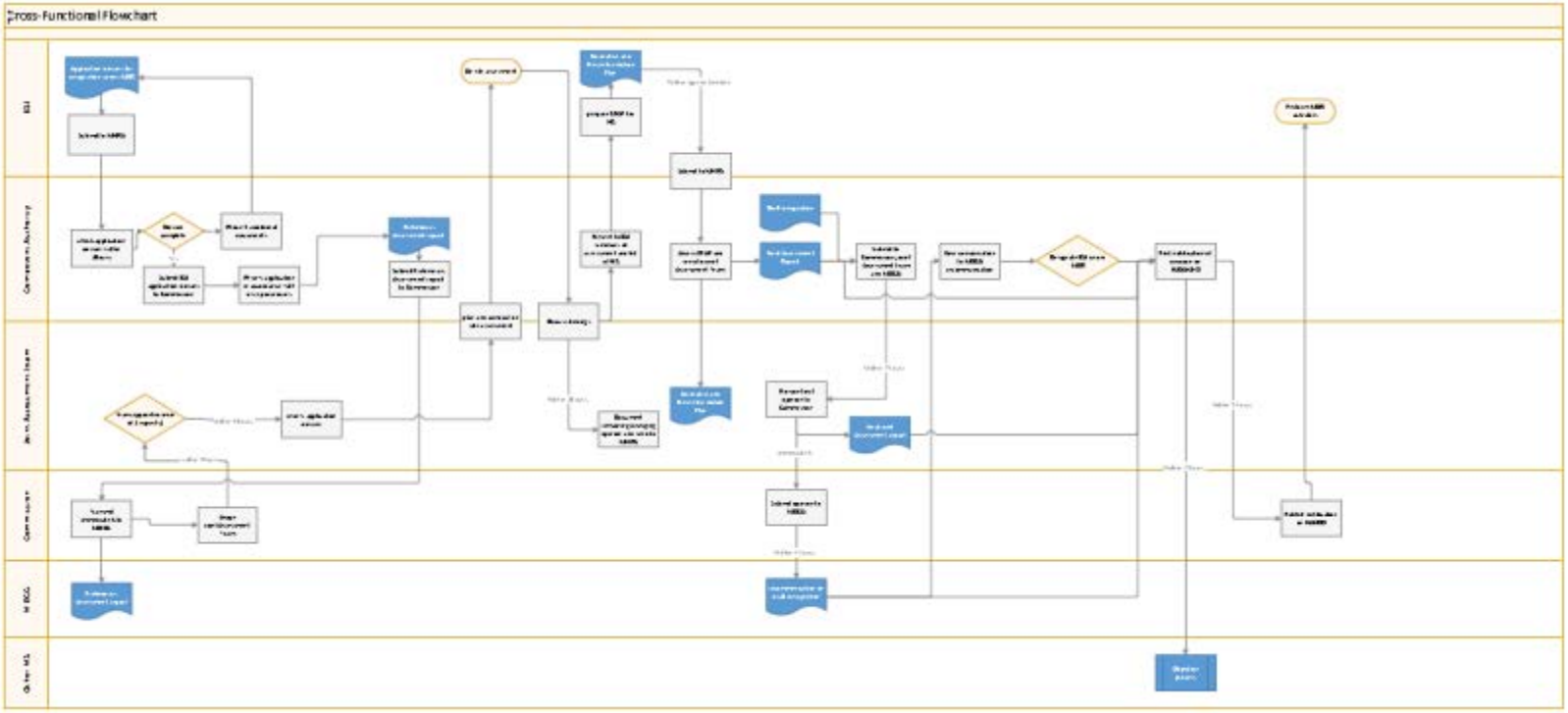
Transition timelines MDR (Article 120)



MDR transition (Article 120)



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.