Council of the European Union
General Secretariat

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Brussels, 07 May 2026

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MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Medical Devices)
Subject:	Regulation to simplify rules on medical and in vitro diagnostic devices - Commission presentation on cluster 3 - Notified bodies, classification and conformity assessment

Delegations will find in annex the presentation by the Commission services at the meeting of the Working Party on Pharmaceuticals and Medical Devices on 7 May 2026.

MDR/IVDR revision
Commission Proposal

DG SANTE Unit D3, Medical devices



European Commission

#HealthUnion

Agenda – Cluster 3

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1. Notified bodies

- Topics: Authorities responsible for notified bodies, requirements to be met by notified bodies, designation and monitoring of notified bodies, coordination of notified bodies, access to notified bodies and fees. (Legal references in MDR/IVDR: Chapter IV, Annex VII, Sections 1 and 2)

2. Classification

- Topics: Classification of devices (except: classification decisions – dealt with under Cluster 2 ‘Support to regulatory system’). (Legal references in MDR: Annex VIII)

3. Conformity assessment

- Topics: Conformity assessment (conformity assessment procedures, special pathways for breakthrough and orphan devices, digitalisation, CECP, mechanism for scrutiny, certificates of conformity, derogations, regulatory sandboxes, certificates of free sale). (Legal references in MDR: Article 2 (74)-(76), Article 3, Chapter V, Section 2, Annex VII, Sections 3 and 4, Annexes IX, X, XI, XII, XIII; Legal references in IVDR: Article 2 (76)-(78))

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Revision of the medical devices regulations

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Overall objective of the MDR / IVDR revision:

Simplify the rules to **reduce administrative burden,** increase **predictability, shorten processes, improve cost-efficiency and effectiveness**, while keeping the **high level of patient safety** and **ensuring the availability** of devices.

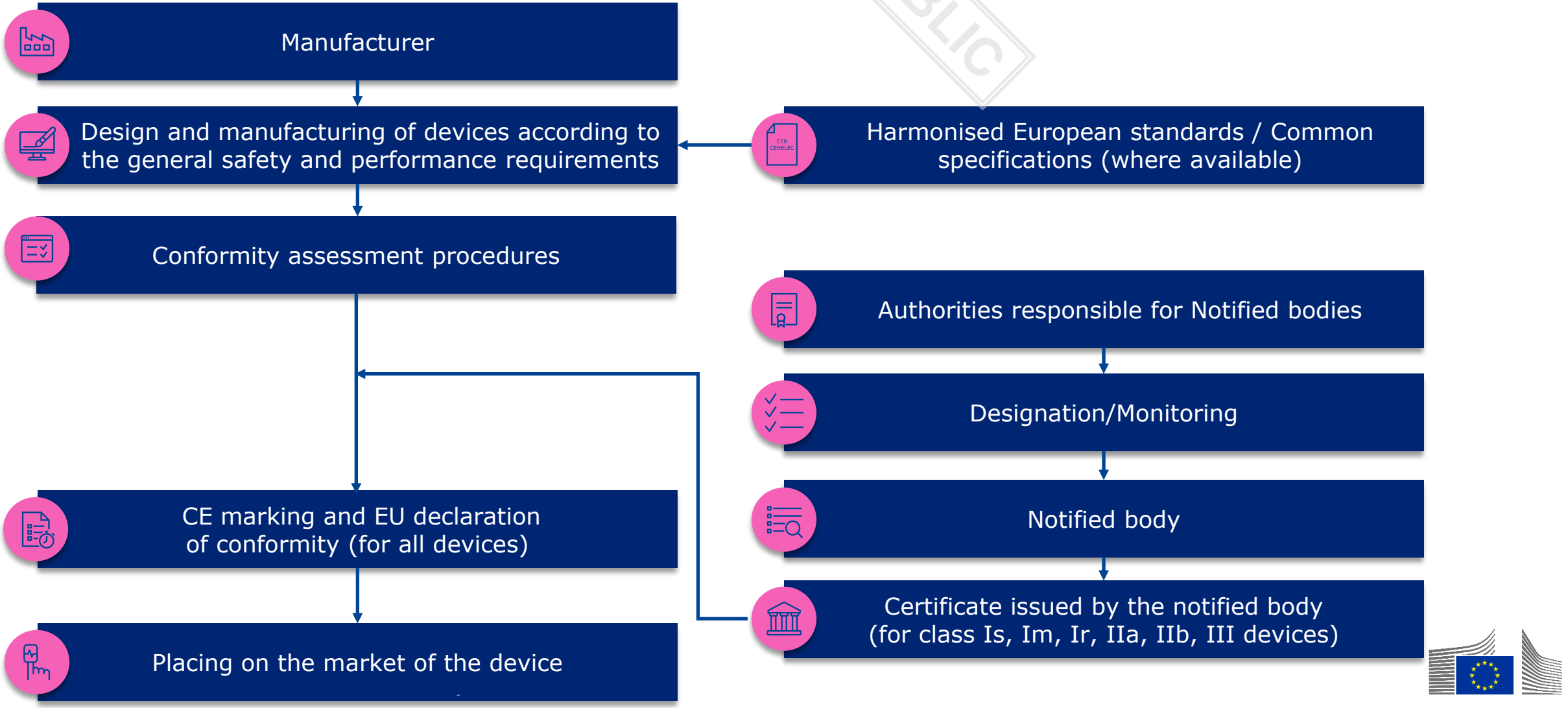


- Revision proposal (covering MDR/IVDR, their annexes)
- supported by two Staff Working Documents: targeted evaluation and cost-savings analysis

The revision will make the sector **more competitive,** in the internal market and globally, **by supporting innovation for better patient care.**

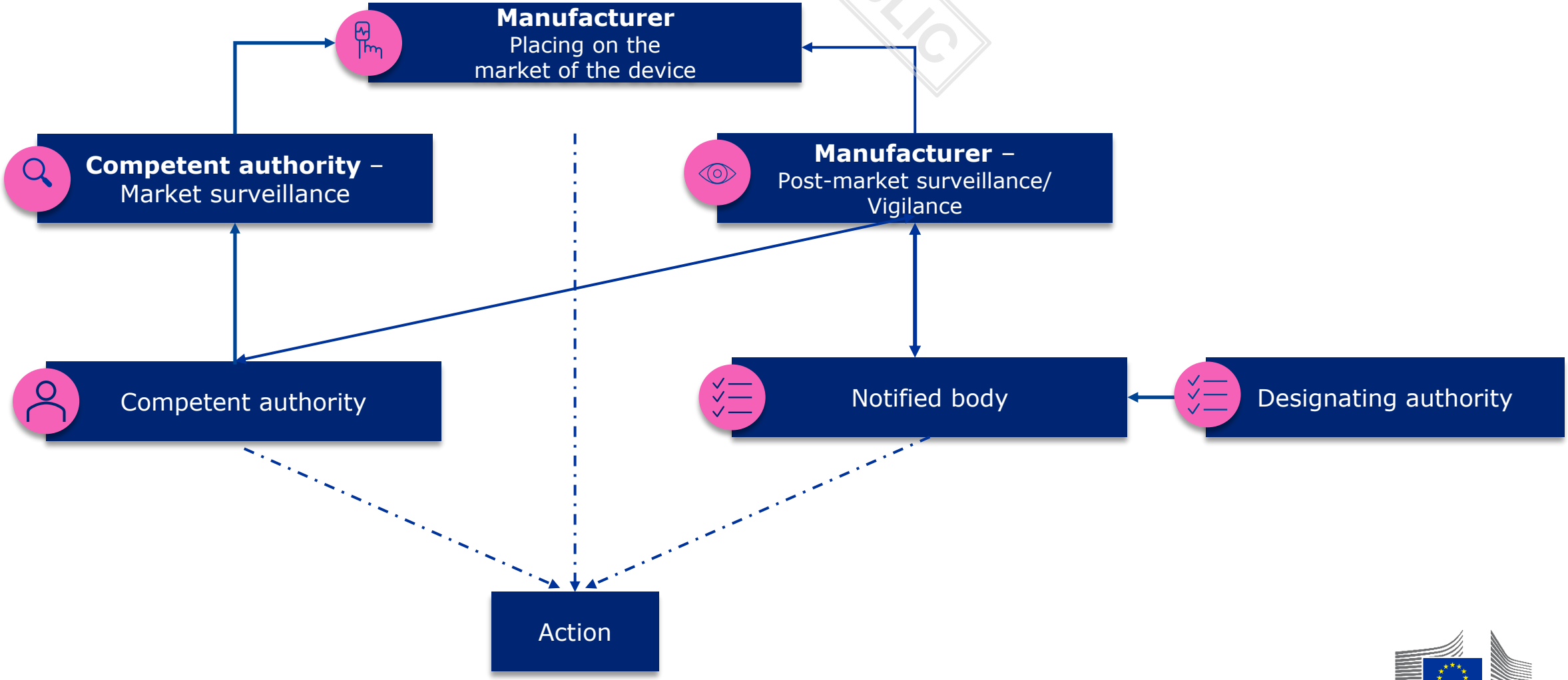
New Legislative Framework (NLF)
Basic operational scheme pre-market UNCHANGED

PUBLIC



New Legislative Framework (NLF)
Basic operational scheme post-market UNCHANGED

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Evaluation – Key findings/problem statement

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Strengthened EU framework for safe and performant medical devices, through stricter pre-/post-market requirements, improved oversight.

Improved safety, evidence quality, and transparency

Confirmed added value of replacing fragmented national rules with a single regulatory framework.

Structural inefficiencies: regulatory complexity, insufficient proportionality, implementation delays, inconsistent application.

Strongly increased **costs and admin burden**, longer certification **timelines**, reduced **predictability**.

Unavailability of devices, especially innovative/niche. Loss of **competitiveness**, esp. for SMEs.

Transition period extensions provided temporary relief, but **core issues remain**.

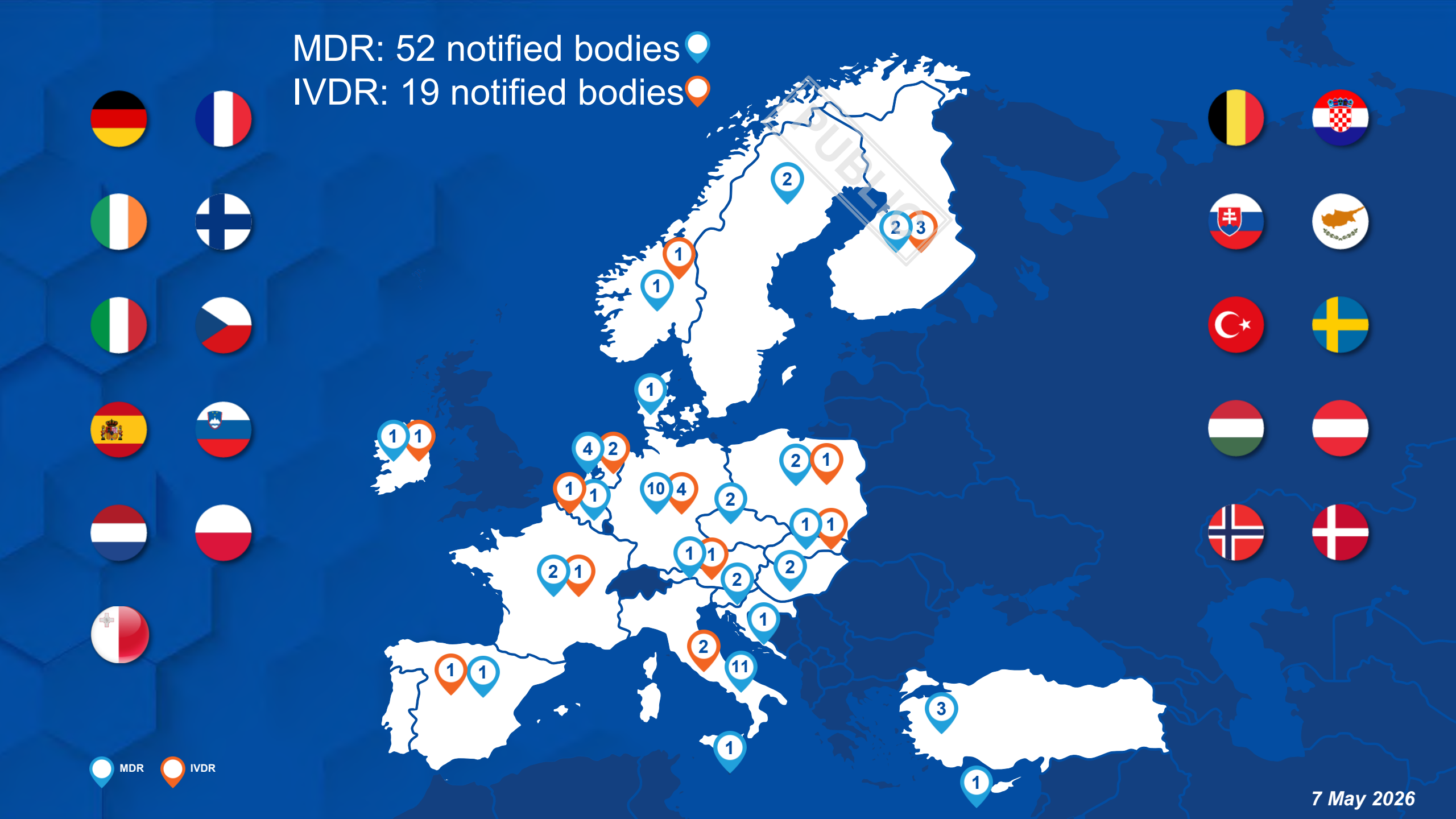
LESSON LEARNED

STRIKING THE RIGHT REGULATORY BALANCE IS CRITICAL



Notified bodies

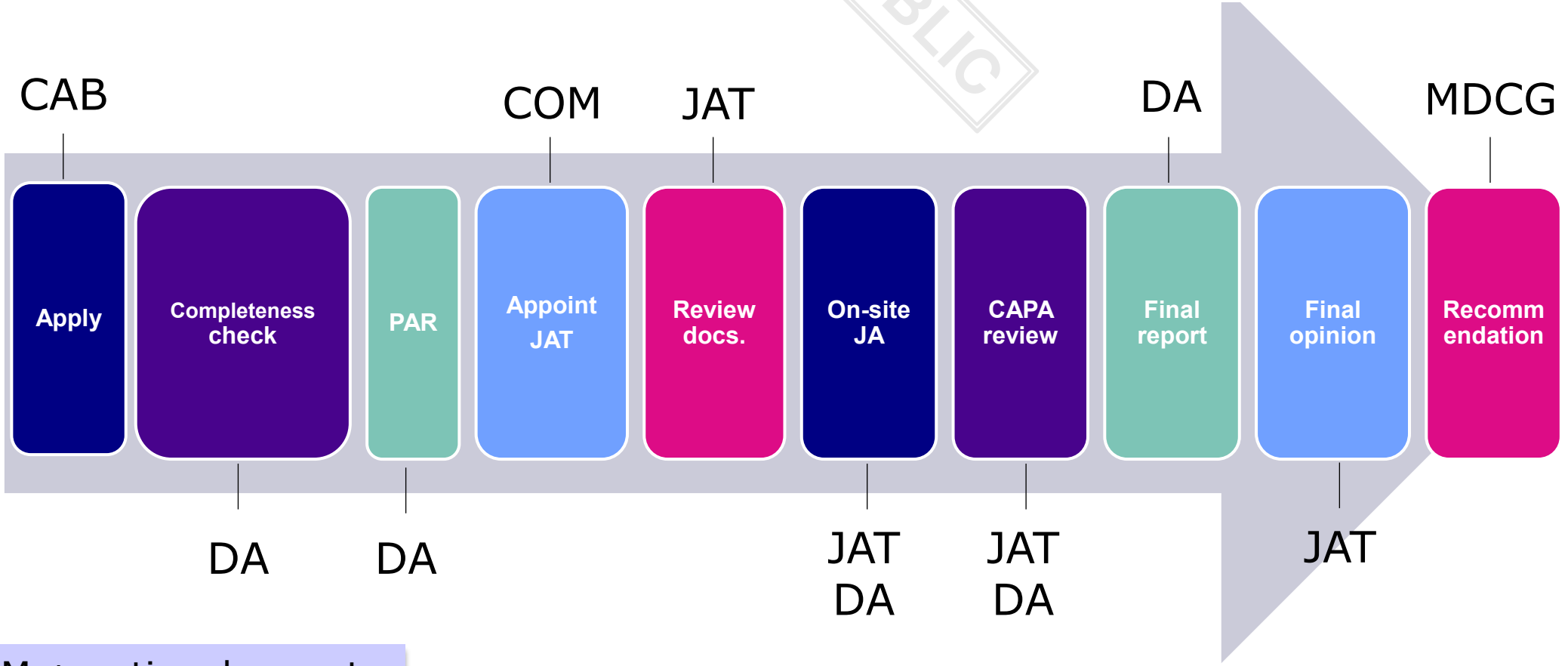
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MDR: 52 notified bodies
IVDR: 19 notified bodies
MDR
IVDR
7 May 2026

Legal reference: MDR Chapter IV / Articles 39 and 42 and IVDR Chapter IV / Articles 35 and 38

Current joint assessment process for **designation** and **re-assessment**

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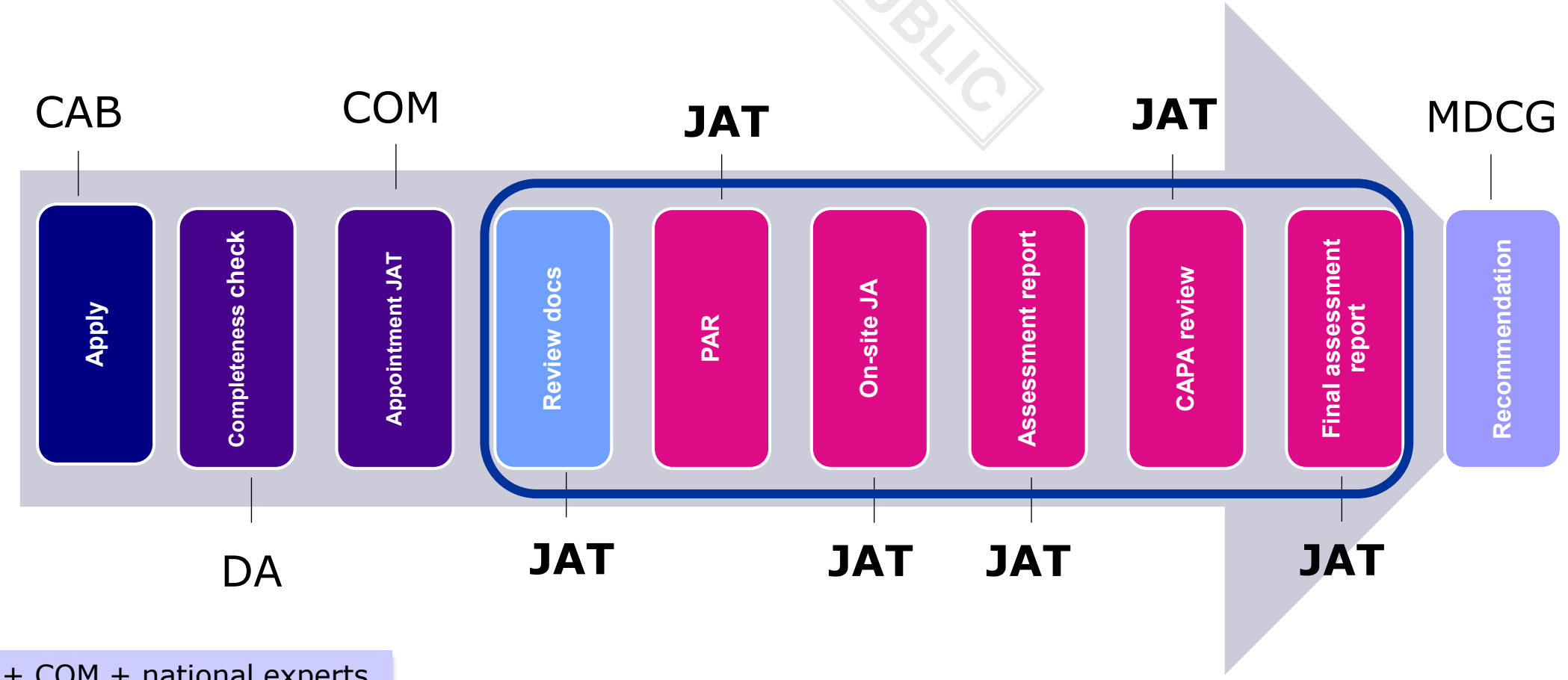
JAT = COM + national experts

CAB: Conformity Assessment Body
JAT: Joint Assessment Team
MDCG: Medical Device Coordination Group
CAPA: Corrective Actions and Preventive Actions
COM: Commission
DA: Designating Authority
PAR: Preliminary Assessment Report

Legal reference: MDR Chapter IV / Articles 39 and 42 and IVDR Chapter IV / Article 31

Proposed joint assessment process for **designation**

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JAT = DA + COM + national experts

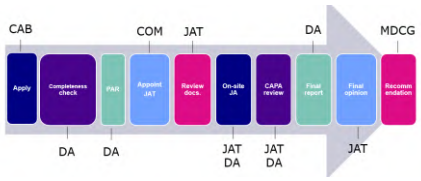
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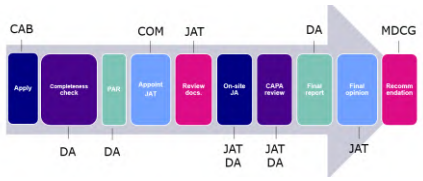
European Commission

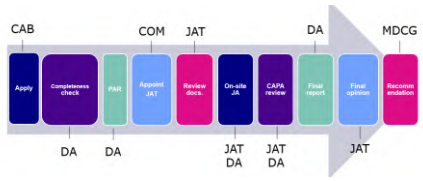
Legal reference: MDR Chapter IV / Article 44 and IVDR Chapter IV / Article 40

Complete re-assessment vs monitoring (1)

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Designation and notification

Complete re-assessment

Complete re-assessment

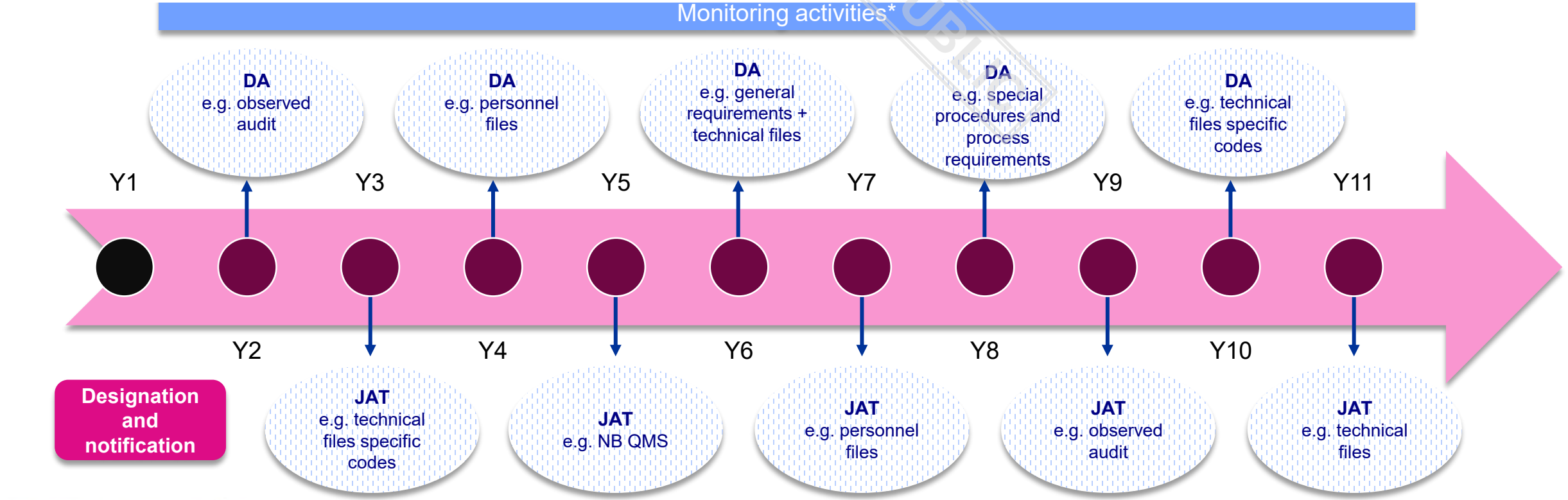
Y1 Y2 Y3 Y4 Y5 Y6 Y7 Y8 Y9 Y10 Y11

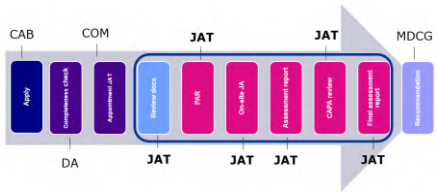
Currently, complete re-assessment every 5 years
Proposal: removal of complete re-assessment process to be replaced by regular monitoring at EU level

Legal reference: MDR Chapter IV / Article 44 and IVDR Chapter IV / Article 40

Complete re-assessment vs monitoring (2)

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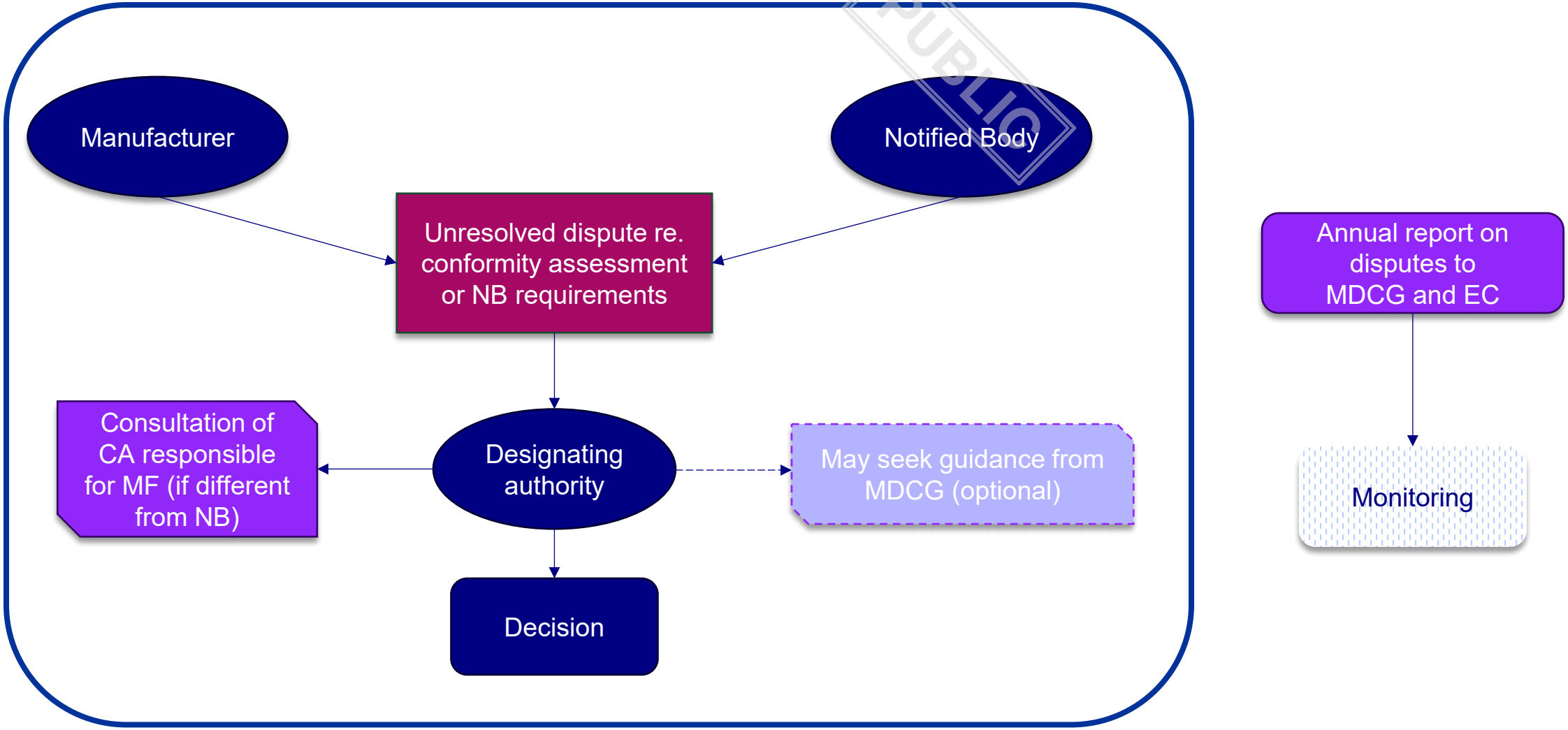


Currently, complete re-assessment every 5 years
Proposal: removal of complete re-assessment process to be replaced by regular monitoring at EU level

* Monitoring activities have targeted scope and can be carried out remotely

Planning for the monitoring activities to be agreed between the NB and the DA (including scope) and to cover several years

New proposed mechanism for dispute resolution – Art. 35 MDR



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Notified bodies – other changes

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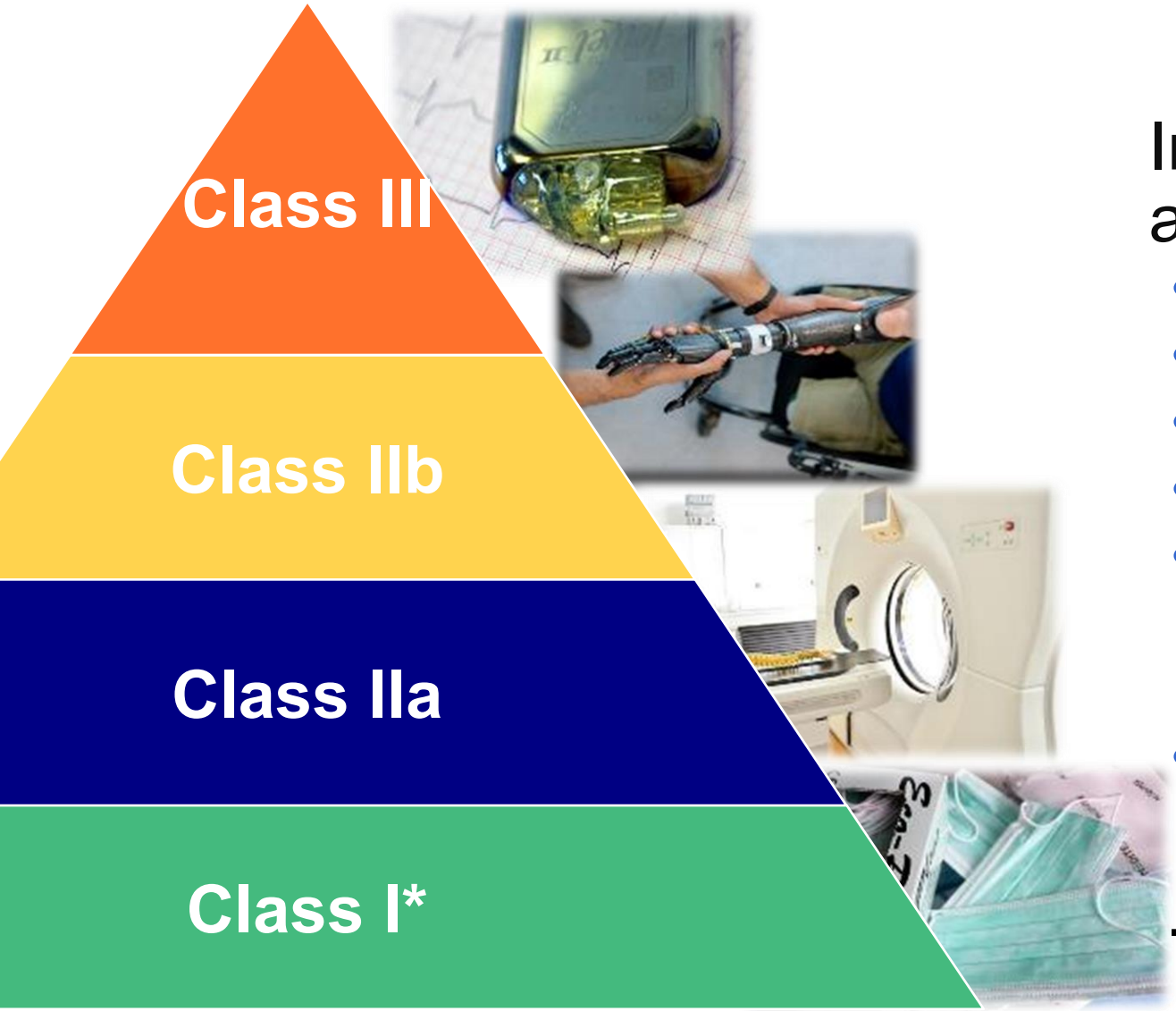
- **Article 36** Requirements relating to notified bodies (notified bodies act in the public interest)
- **Article 40** Nomination of national experts for joint assessment
- **Article 40a** Funding of activities related to designation and monitoring (fee to notified bodies)
- **Article 41** Language requirements (availability of translation of documents)
- **Article 46** Changes to designation and notification (designation and notification process to be applied in case of significant extension and flexibility on the on-site element of the assessment)
- **Article 47** Challenge to the competence of notified bodies (text clarified and adapted to the proposal)
- **Article 48** Exchange of experience between authorities (removal of mandatory peer reviews, which remain part of the exchange of experience between authorities)
- **Article 49** coordination of notified bodies (strengthen the role of the coordination group of notified bodies (NBCG-Med) and link it to MDCG)
- **Article 50** access to notified bodies and fees (list of notified bodies' fees, fee reduction and access to conformity assessment activities, empowerment to specify structure and level of fees, obligation to deal with requests for conformity assessment activities, request to accept application in the interest of public health or patient health or safety)
- **Annex VII Sections 1 and 2**: clarification of requirements relating to notified bodies that are part of a larger organisation, liability and participation to NBCG-Med



Classification of devices

European Commission

Risk classes & factors determining them



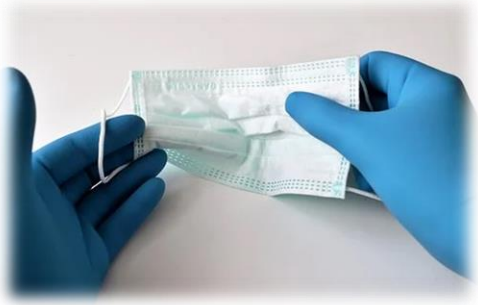
Intended purpose of the devices and their inherent risks due to:

- duration of contact with the body
- degree of invasiveness
- local vs. systemic effect
- potential toxicity
- the part of the body affected by the use of the device – most critical use
- if the device depends on a source of energy

The strictest rule will apply.

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Class I



Wheelchairs and walking aids

Stethoscopes

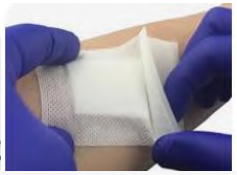
Reusable surgical instruments

Examination gloves

Refrigerator for blood & plasma

Class I reusable, sterile, measuring







Reusable scalpels, scissors, hooks etc.

Sterile wound dressing

Measuring cup/spoon

Class IIa



Diagnostic ultrasound machine

Magnetic resonance imaging system

Bacterial/viral filter for use on patient

Hydrocolloid plaster for blisters

Dental filling materials

Class IIb



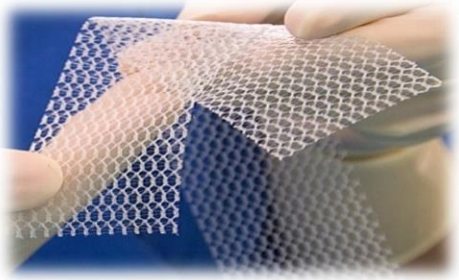
Infusion pumps
In vivo dosimeters

Ventilators

Movement monitor for babies

Diagnostic devices emitting ionizing radiation

Class III





Cardiac catheters

Breast implants

Surgical meshes

Joint replacements

Drug-eluting stents

Prosthetic heart valves

Implementing rules - devices used in combination with another device

DRAFT

Current wording	Proposed revised wording
3.2. If the device in question is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices.	3.2. If the device in question is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices.
Accessories for a medical device shall be classified in their own right, separately from the device with which they are used.	Accessories for a medical device **and accessories for a product listed in Annex XVI** shall be classified in their own right separately from the device with which they are used.

Legal reference: Annex VIII, 4.2

Rule 2: blood bags

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Current wording

All non-invasive devices intended for channelling or storing blood, body liquids, cells or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are classified as class IIa:

[…]

– if they are intended for use for channelling or storing blood or other body liquids or for storing organs, parts of organs or body cells and tissues, **except for blood bags; blood bags are classified as class IIb**.

In all other cases, such devices are classified as class I.



Proposed revised wording

All non-invasive devices intended for channelling or storing blood, body liquids, cells or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are classified as class IIa:

[…]

– if they are intended for use for channeling or storing blood or other body liquids or for storing organs, parts of organs or body cells and tissues, **except for blood bags; by derogation from any other classification rule, blood bags are classified as class IIb.**

In all other cases, such devices are classified as class I.

Legal reference: Annex VIII, 5.2

Rule 6: reusable surgical instruments

PUBLIC

Current wording (rule 6)

All surgically invasive devices intended for transient use are classified as class IIa unless they:

[…]

– are reusable surgical instruments, in which case they are classified as class I;

Proposed revised wording (rule 6)

All surgically invasive devices intended for transient use are classified as class IIa unless they:

[…]

– are reusable surgical instruments regardless of the body part with which they come into contact, in which case they are classified as class I

Annex VIII, 2.3: ‘Reusable surgical instrument’ means an instrument intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and which is intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilisation have been carried out.

Legal reference: Annex VIII, 5.3

Rule 7: reusable surgical instruments

PUBLIC

Current wording (rule 7)

All surgically invasive devices intended for short-term use are classified as class IIa unless they:

[…]

Proposed revised wording (rule 7)

All surgically invasive devices intended for short-term use are classified as class IIa unless they:

[…]

– are reusable surgical instruments regardless of the body part with which they come into contact, in which case they are classified as class I

Annex VIII, 2.3: ‘Reusable surgical instrument’ means an instrument intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and which is intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilisation have been carried out.

Rule 8: accessories to active implants

PUBLIC

Current wording

All implantable devices and long-term surgically invasive devices are classified as class IIb unless they:

[…]

- are **active implantable devices or their accessories**, in which cases they are classified as class III;

Proposed revised wording

All implantable devices and long-term surgically invasive devices are classified as class IIb unless they:

[…]

- are **active implantable devices**, in which cases they are classified as class III;

Annex VIII, 3.2: accessories for a medical device are classified in their own right separately from the device with which they are used.

Legal reference: Annex VIII, 5.4

Rule 8: components of joint replacements and spinal implants

PUBLIC

Current wording

All implantable devices and long-term surgically invasive devices are classified as class IIb unless they:

[…]

- are total or partial joint replacements, in which case they are classified as class III, with the exception **of ancillary components such as screws, wedges, plates and instruments**; or
- are spinal disc replacement implants or are implantable devices that come into contact with the spinal column, in which case they are classified as class III **with the exception of components such as screws, wedges, plates and instruments.**

Proposed revised wording

All implantable devices and long-term surgically invasive devices are classified as class IIb unless they:

[…]

- are total or partial joint replacements, in which case they are classified as class III, **with the exception of components such as screws, wedges, plates and instruments and other devices that are well-established technology devices**; or
- are spinal disc replacement implants or are implantable devices that come into contact with the spinal column, in which case they are classified as class III, **with the exception of components such as screws, wedges, plates and instruments and other devices that are well-established technology devices**.

Legal reference: Annex VIII, 6.1

Rule 9: active devices

PUBLIC

Current wording

All **active therapeutic devices** intended to administer or exchange energy are classified as class IIa unless their characteristics are such that they may administer energy to or exchange energy with the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are classified as class IIb.

All active devices intended to control or monitor **the performance of active therapeutic class IIb devices**, or intended directly to influence the performance of such devices are classified as class IIb.

Proposed revised wording

All **active therapeutic devices and all active products listed in Annex XVI** intended to administer or exchange energy are classified as class IIa unless their characteristics are such that they may administer energy to or exchange energy with the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are classified as class IIb.

All active devices intended to control or monitor **the performance of active therapeutic class IIb devices, and of any active product listed in Annex XVI falling in class IIb**, or intended directly to influence the performance of such devices are classified as class IIb.

Legal reference: Annex VIII, 6.3

Rule 11: software

PUBLIC

Current wording

Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:

– **death or an irreversible deterioration** of a person's state of health, in which case it is in **class III**; or

– **a serious deterioration** of a person's state of health or a surgical intervention, in which case it is classified as **class IIb**.

Software intended to **monitor physiological processes** is classified as **class IIa**, except if it is intended for monitoring of **vital physiological** parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as **class IIb**.

All other software is classified as **class I**.

Proposed revised wording

Software which is intended to generate an output that confers a clinical benefit and is used for diagnosis, treatment, prevention, monitoring, prediction, prognosis, compensation or alleviation of a disease or condition is classified as **class I**, unless the output is intended for a disease or condition:

– in a **critical situation** with a risk of causing **death or an irreversible deterioration** of a person's state of health, in which case it is classified as **class III**;

– in a **serious situation** with a risk of causing a **serious deterioration** of a person's state of health or a surgical intervention, or to **drive clinical management** in a **critical situation** in which cases it is classified as **class IIb**

– in a **non-serious situation**, or to **drive clinical management in a serious situation** or to inform **clinical management** in a **critical or serious situation** in which cases it is classified as **class IIa**

Current wording

State of Healthcare situation or patient condition		Significance of Information provided by the MDSW to a healthcare situation related to diagnosis/therapy		
		High Treat or diagnose ~ IMDRF 5.1.1	Medium Drives clinical management ~ IMDRF 5.1.2	Low Informs clinical management (everything else)
	Critical situation or patient condition ~ IMDRF 5.2.1	Class III Category IV.i	Class IIb Category III.i	Class IIa Category II.i
	Serious situation or patient condition ~ IMDRF 5.2.2	Class IIb Category III.ii	Class IIa Category II.ii	Class IIa Category I.ii
	Non-serious situation or patient condition (everything else)	Class IIa Category II.iii	Class IIa Category I.iii	Class IIa Category I.i

Proposed revised wording

PUBLIC

State of Healthcare situation or patient condition		Significance of Information provided by the MDSW to a healthcare situation related to diagnosis/therapy		
		High Treat or diagnose ~ IMDRF 5.1.1	Medium Drives clinical management ~ IMDRF 5.1.2	Low Informs clinical management (everything else)
	Critical situation or patient condition ~ IMDRF 5.2.1	Class III Category IV.i	Class IIb Category III.i	Class IIa Category II.i
	Serious situation or patient condition ~ IMDRF 5.2.2	Class IIb Category III.ii	Class IIa Category II.ii	Class IIa Category I.ii
	Non-serious situation or patient condition (everything else)	Class IIa Category II.iii	Class I Category I.iii	Class I Category I.i

Legal reference: Annex VIII, 7.6

Rule 19: nanomaterial

PUBLIC

Current wording

All devices **incorporating or consisting of nanomaterial** are classified as:

- class III if they present a high or medium potential for internal exposure;
- class IIb if they present a low potential for internal exposure; and
- class IIa if they present a negligible potential for internal exposure.

Proposed revised wording

All devices **incorporating or consisting of nanomaterial as defined in Commission Recommendation C/2022/3689** are classified as:

- class III if they present a high or medium potential for internal exposure;
- class IIb if they present a low potential for internal exposure; and
- class IIa if they present a negligible potential for internal exposure.

Article 2, points (18) to (21) MDR: proposal to delete the definitions of ‚nanomaterial', ‚particle', ‚agglomerate' and ‚aggregate'.

Legal reference: Annex VIII, 7.8

Rule 21: substance-based devices

PUBLIC

Current wording

Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body are classified as:

- class III if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose;
- […]

Proposed revised wording

Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed **on or** in the human body are classified as:

- class III if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose;
- […]



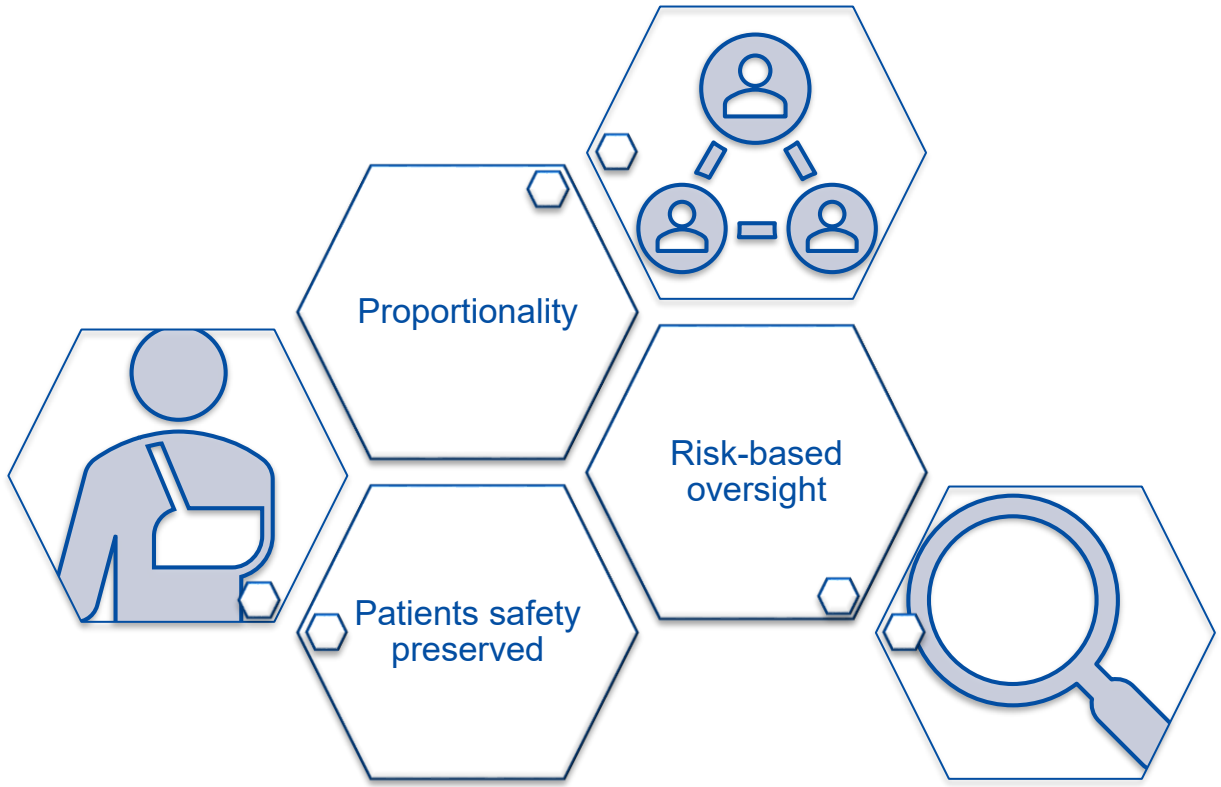
Conformity assessment

European Commission

Conformity Assessment Procedures

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Simplify rules while maintaining high level patient safety standards



Changes to the **involvement of notified bodies**

- No changes to **initial certification** for high risk devices and targeted changes for other devices – same rigours pre-market assessment
- **Post-market** adjustment – for manufacturers of good track records and low-risk profile

PUBLIC

Conformity Assessment Procedures - Key changes

Pre-market

- No change in the involvement of the notified body for high risk devices (class III and IIb implantable that are not WET)
- Sampling of the technical documentation for class IIb and IIa of one representative + possible **for cause*** assessment
- For class IIa assessment of the technical documentation excluding the design stage applied to the device

Post- market

- Certification cycle based on proportionate peer review
- Possibility to reduced the frequency of surveillance audits in light of previous results and if no concerns are raised
- unannounced / short notice audits to be performed when justified
- Sampling of the technical documentation to be performed **for cause***
- Notified bodies to review serious incidents related to a serious public health threat or any field safety corrective action and to evaluate PSURs during surveillance activities

*for cause: Not to be performed only as reaction to an event. In particular:

- For the sampling pre-market, linked to outcome of QMS assessment / technical documentation and based on the judgment of the notified body (e.g. missing / unclear information, detected non-conformities)
- For the sampling post-market, linked to concerns on post-market surveillance data or to duly justified grounds, e.g. lack of post-market information, open non-conformities

Key adjustment – Post-market oversight

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Topic	Current situation (one-size-fit-all)	Proposal
Certification cycle	Re-certification every 5 years max	**Periodic Review**: • no fixed cycle • validity can be limited as needed • no changes to nature and depth of the assessment
Surveillance Audits	Annual	Possible **frequency reduction** (max every 24 months) if good compliance history and no concerns from post-market surveillance / vigilance
Unannounced audits	Once at least every 5 years	To be carried out **when justified**
Technical Documentation Sampling	Systematic and continuous sampling for medium-risk devices	**Risk-based sampling**: to be performed based on the outcome of the notified body's assessment and the information available from post-market surveillance / vigilance
Notified bodies Evaluation of Post-Market Data	Review all vigilance data in parallel with CAs	**Signal detection**, review of certain individual serious incidents, all FSCAs, and any other incident upon request from CAs

Legal reference: Article 52a2 and 52a3

Conformity assessment of breakthrough devices and of orphan devices – **Criteria**

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Breakthrough device criteria

(a) […] **high degree of novelty** with respect to the device **technology**, related clinical **procedure** or the **application** of the device in clinical practice;
(b) […] **significant positive clinical impact** on patients or public health, for a **life-threatening or irreversibly debilitating** disease or condition, by either of the following:

(i) offering a significant positive clinical or health impact compared to available alternatives and the state of the art;
(ii) fulfilling an unmet medical need where there is an absence or insufficiency of available alternative options for that purpose.

Orphan device criteria

(a) […] treatment, diagnosis, or prevention of a disease or condition that presents in not **more than 12 000 individuals** in the Union per year;
(b) at least one of the following criteria is met:

(i) there are i**nsufficient available alternatives**;
(ii) the device is expected to provide a **clinical benefit** compared to available alternatives or the state of the art, **taking into account** both **device-specific** factors and **patient population-specific factors.**

Legal reference: Article 52a2 and 52a3

Conformity assessment of breakthrough devices and of orphan devices – **Process**

PUBLIC

Designation & advice (5)

- Expert panel opinion on if device x meets criteria (+/-)
- Expert panel advice on clinical development strategy & […] (if requested)

Conformity assessment with NB (6)

- Prioritises and facilitate rolling review (6)
- May issue certificate if certain conditions fulfilled AND if necessary limit validity of certificate and/or require manufacturers to conduct post-market clinical follow-up activities within X amount of time (7)

Operational and (more) detailed arrangements

Legal reference: 52a8 and 9

PUBLIC

52a(8) – Delegated Acts

- To adapt to technical or scientific progress or to take into account developments regarding conformity assessment of breakthrough devices or orphan devices at international level.
- Adopted in accordance with Article 115.

52a(9) – Implementing Acts

- To lay down details of the procedure for the conformity assessment.
- Adopted in accordance with the examination procedure referred to in Article 114(3).

Derogations

Legal reference: Articles 59 and 59a

PUBLIC

Art. 59: Derogation from the conformity assessment procedures

- Clarification on limited period of time
- Extension to diagnostic or therapeutic services
- Information about authorisation to be made publicly available
- Involvement of expert panels in case of extension of national derogation to EU
- Empowerment for COM to grant EU wide authorisation in case of a public health emergency without prior national derogation

Art. 59a: Derogations from certain requirements in the event of a serious cross-border threat to health, disaster or crisis

- Possibility for time-limited derogations from certain requirements (e.g. design, manufacturing or intended purpose changes) in relation to CE-marked devices if justified for public health, patient safety or patient health
- No derogation from general safety and performance requirements
- Possibility to extend national exemption to EU in exceptional cases relating to public health

Legal reference: Article 2 (74)-(76) & Articles 59b and c

Regulatory sandboxes National and Union

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2(74) 'regulatory sandbox' means a **controlled environment** set up by a competent authority […] to **develop, test, validate and use, where appropriate in real-world conditions**, an innovative **product or technology** pursuant to a sandbox plan for a limited time […]

Device focused: Innovation/SME support mechanism to support testing under controlled environments.

e.g. Manufacturer of a Machine Learning medical device software intended for diagnosis of cancerous lesions in mammograms would like to further develop, test and validate this ML in a hospital setting in X Member State.

2(76) 'Union regulatory sandbox' means a **controlled environment** set up by the Commission for **testing alternative or new regulatory requirements or enforcement practices** and **appraising their validity in comparison with existing requirements** […] for a limited time.

Process and or compliance pathway focused: Do the requirements of the MDR sufficiently accommodate for X technology and/or are there any specific requirements that are inadequate/inapplicable?

e.g. medical device production systems technologies (e.g., CAD/CAM systems in dentistry) challenging to approach device by device or as a 'system'

European Commission

Legal reference: 59 (b)

National regulatory sandboxes (preparation and agreement) 1/2

PUBLIC

What devices: Art. 59(b)(3):

a) **Device** is expected to address **unmet medical needs** or to provide a **significant clinical benefit** to patients or to the health system […]
(b) the **application x y or z requirements** would impede or significantly delay the development and access […]

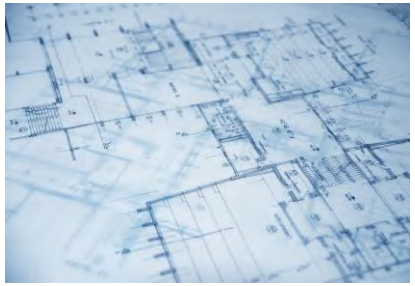


What happens: Art. 59(b)(1)).



In that sandbox, **certain requirements** […] would not be appropriate and are **'adapted' or 'waived'** during the course of the **time limited** sandbox

How ? 59(b)(2)



How ? 59(b)(2) the activities shall take according to a **sandbox plan** that shall clearly identify the requirements of this Regulation referred to in **paragraph 1**, which […] are temporarily adapted or waived.

Art. 2(75) 'sandbox plan' means a **document** […] with objectives, conditions, timeframe, methodology and requirements

59(b)(4) MS may ask expert panels for their input on sandbox plan

European Commission

National regulatory (running and output) 2/2

PUBLIC

Running: Art. 59(b)(5):

Device is expected to address **unmet medical needs** or to provide a **significant clinical benefit** to patients or to the health system […] in sandbox according to sandbox plan.



Participant identifies **'any harm'** in relation to the implementation of sandbox **& informs NCA**

NCA takes corrective action & can suspend, revoke or restrict scope

Information disclosure: Art. 59(b)(7)

NCA **informs COM and MDCG** about

- **Establishment** of a sandbox
- Keep them informed about **implementation & outcome**

Assurance: 59(b)(6)

Manufacturers remain liable under applicable Union and national law for any damages

Union regulatory sandboxes

PUBLIC

What: Art. 59(c)(1):
COM initiative or substantiated **request by MS establishes** (via IA) **sandbox based on a plan & for a limited time**

Inform whether existing requirements are sufficient or appropriate for X device (or device type)

Information disclosure: Art. 59(c)(3)

COM shall inform MDCG
- **Establishment** of a sandbox
- Keep informed about **implementation & outcome**

59(c)(2) COM **shall** ask expert panels for their input on sandbox plan



Prerequisite: existing requirements
a) impede […] development and access
b) would not adequately protect [...] patients [...]

Operational and (more) detailed arrangements

Legal reference: 59 (c)

PUBLIC

59 (c) (4) – Implementing Acts

- To further specify common principles or the detailed arrangements for the establishment, operation and supervision of:

1. National sandboxes
2. Union sandboxes

- Adopted in accordance with the examination procedure referred to in Article 114(3).

59 (c) (5) – Delegated Acts

- Adapt sandbox rules (both national and Union) to scientific, technical or regulatory progress and to take into account developments […], including in areas other than medical devices.
- Adopted in accordance with Article 115.

Legal reference: Article 60

Certificates of free sales

PUBLIC

Current wording

1. For the purpose of export and upon request by a manufacturer or an authorised representative, the Member State in which the manufacturer or the authorised representative has its registered place of business shall issue a certificate of free sale declaring […]

Where a notified body has issued a certificate pursuant to Article 56, the certificate of free sale shall set out the unique number identifying the certificate issued by the notified body, […]

2. The Commission may, by means of implementing acts, establish a model for certificates of free sale, taking into account international practice as regards the use of certificates of free sale. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 114(2)

Proposed revised wording

1. For the purpose of export […]

1a. The person referred to in Article 22(1) or (3) may request the competent authority of the Member State where it is established to issue a certificate of free sale for a **system or procedure pack** for which it has drawn up a statement in accordance with Article 22.

1b. The competent authority shall make the certificates of free sale issued in accordance with paragraphs 1 and 1a **publicly available in Eudamed**.

2. The Commission may, by means of implementing acts […]

Legal reference: MDR Article 52b and IVDR Article 48b

Digitalisation

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Manufacturer may draw up and make available technical documentation, reports and other relevant documents in digital format

Possibility for common specifications to establish minimum requirements on functional specifications for the digital format

Conformity Assessment – other changes

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- **Article 52:**
  - for class I that are reusable surgical instrument no involvement of notified body if the manufacturer applied harmonised standards or common specifications,
  - simplified conformity assessment procedures for WET,
  - availability of documents in a language that is accepted by the notified body,
  - clarification and extension of empowerments for implementing acts and new empowerment for delegated act to amend Annexes IX, X, XI and XIII.
- **Article 54:** Clinical evaluation consultation procedure for class III implantable devices and possibility for the Commission to extend the list based by delegated acts. Removal of annual overview.
- **Article 55:** Mechanism of scrutiny to address concerns raised by MDCG or the Commission in relation to safety and performance of any device, requiring an advice from the expert panel.
- **Annex VII Sections 3 and 4**: availability of internal personnel for certain functions and their experience and clarification on certain process requirements, including e.g. predetermined change control plan and rolling reviews.
- **Annex IX**: Reduced timelines for consultation of medicines and SoHO authorities.

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