The EU Regulations on medical devices and *in vitro* diagnostic medical devices

Information session for international regulators and stakeholders

4 July 2024

Peter Bischoff-Everding
European Commission
Directorate-General for Health and Food Safety (DG SANTE)
Unit D.3 – Medical Devices

Agenda

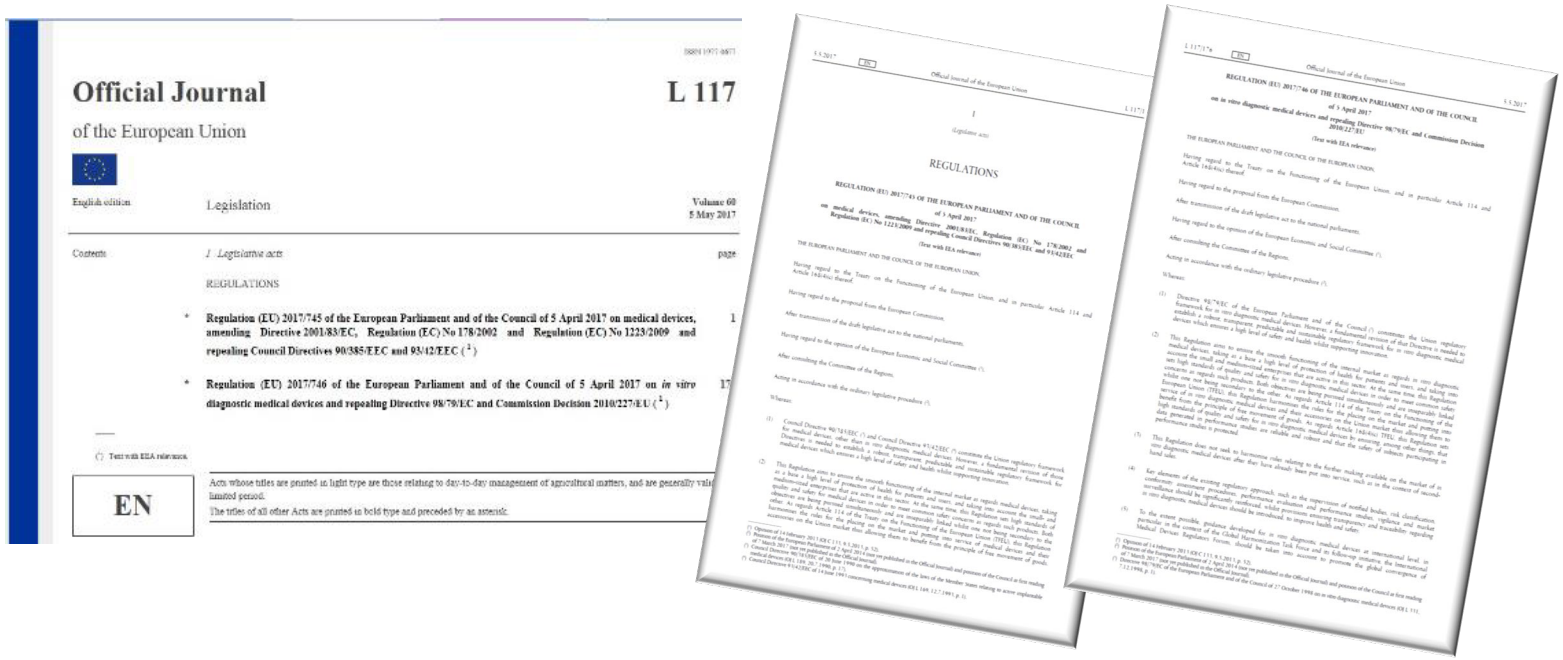
Housekeeping rules

1. *please indicate your organisation and name („edit display name“)*
2. *please mute your microphone, when you don‘t speak;*
3. *use the ‚raise your hand‘ button, if you want to speak*

1. Welcome and scene setter
2. State of play of implementation
   - Regulation (EU) 2017/745 on medical devices (MDR)
   - Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR)
3. Q&A
4. Demo of EUDAMED, UDI, EMDN

Regulatory framework

- Regulation (EU) 2017/745 on medical devices (MDR)
  - applicable since 26 May 2021, plus extra transitional period for ‚legacy devices'
- Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR)
  - applicable since 26 May 2022, plus extra transitional period for ‚legacy devices'



European Commission

Objectives

"*robust, transparent, predictable and sustainable regulatory framework […] which ensures a high level of safety and health whilst supporting innovation*"

Achievements

49 MDR notified bodies (13 applications ongoing)

~8,000 MDR certificates issued

12 IVDR notified bodies (9 applications ongoing)

~900 IVDR certificates issued

Expert panels (hosted by EMA)

EU Reference Laboratories

EUDAMED modules (Actors, UDI/DEV, NB/Certificates) in use

Challenges

Limited capacity of notified bodies

Length and costs of conformity assessment

Stricter requirements (especially pre-market clinical data)

Risk of shortages

Delay of EUDAMED

Remedies

More time to transition from MDD/AIMDD/IVDD to MDR and IVDR (i.e. extension of MDR and IVDR transitional periods)

No lowering of quality and safety requirements

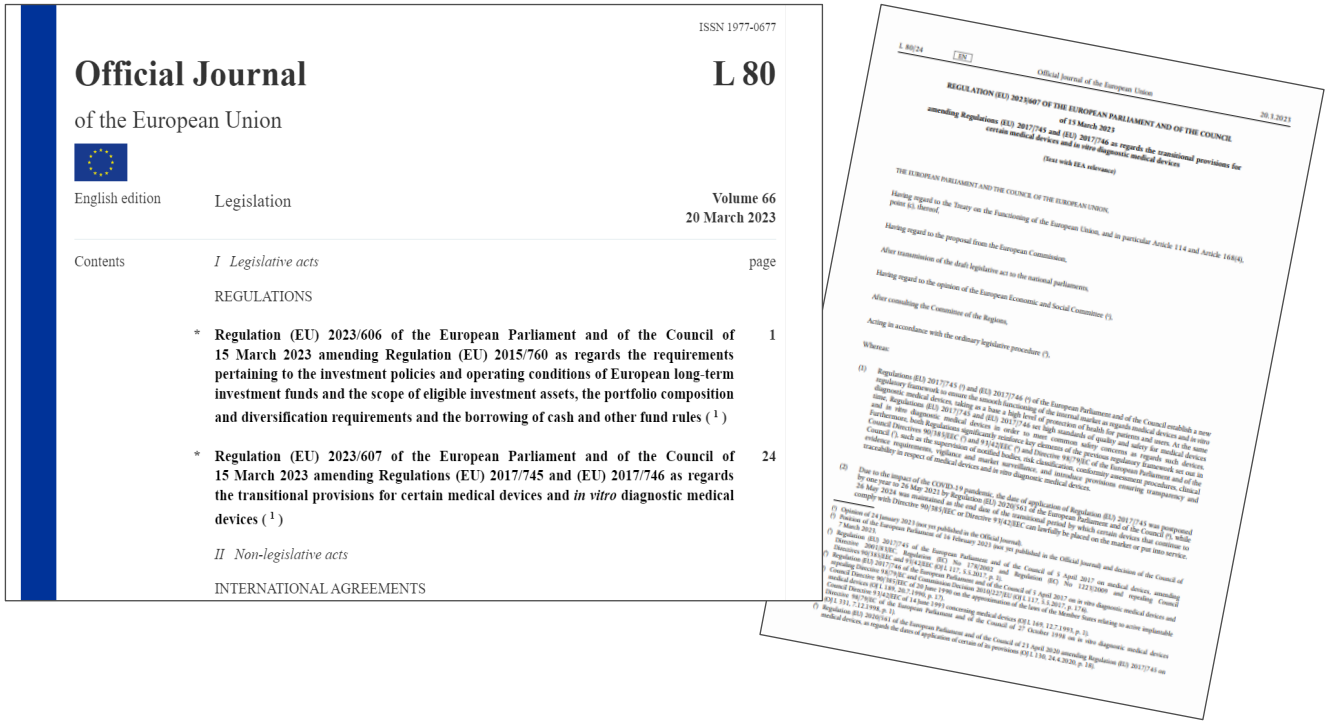
MDCG guidance supporting the transition

Growing number of "harmonised standards" and extended standardisation mandate

EU4Health Program projects

Extension of MDR transitional period

- Regulation (EU) 2023/607 of 15 March 2023 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices



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English edition — Legislation — Volume 66, 20 March 2023

Contents — page

I Legislative acts

REGULATIONS

* **Regulation (EU) 2023/606 of the European Parliament and of the Council of 15 March 2023 amending Regulation (EU) 2015/760 as regards the requirements pertaining to the investment policies and operating conditions of European long-term investment funds and the scope of eligible investment assets, the portfolio composition and diversification requirements and the borrowing of cash and other fund rules** [1] — 1

* **Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices** [1] — 24

II Non-legislative acts

INTERNATIONAL AGREEMENTS

L 80/24 — EN — Official Journal of the European Union — 20.3.2023

REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 March 2023

amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4), point (c), thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee (1),

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure (2),

Whereas:

(1) Regulations (EU) 2017/745 (3) and (EU) 2017/746 (4) of the European Parliament and of the Council establish a new regulatory framework to ensure the smooth functioning of the internal market as regards medical devices and in vitro diagnostic medical devices, taking as a basis a high level of protection of health for patients and users. At the same time, Regulations (EU) 2017/745 and (EU) 2017/746 set high standards of quality and safety for medical devices and in vitro diagnostic medical devices in order to meet common safety concerns as regards such devices. Furthermore, both Regulations significantly reinforce key elements of the previous regulatory framework set out in Council Directives 90/385/EEC (5) and 93/42/EEC (6) and Directive 98/79/EC of the European Parliament and of the Council (7), such as the supervision of notified bodies, risk classification criteria, conformity assessment procedures, clinical evidence requirements, vigilance and market surveillance, and introduce provisions ensuring transparency and traceability in respect of medical devices and in vitro diagnostic medical devices.

(2) Due to the impact of the COVID-19 pandemic, the date of application of Regulation (EU) 2017/745 was postponed by one year to 26 May 2021 by Regulation (EU) 2020/561 of the European Parliament and of the Council (8), while 26 May 2024 was maintained as the end date of the transitional period by which certain devices that continue to comply with Directive 90/385/EEC or Directive 93/42/EEC can lawfully be placed on the market or put into service.

(1) Opinion of 24 January 2023 (not yet published in the Official Journal).

(2) Position of the European Parliament of 16 February 2023 (not yet published in the Official Journal) and decision of the Council of 7 March 2023.

(3) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

(4) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

(5) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).

(6) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

(7) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

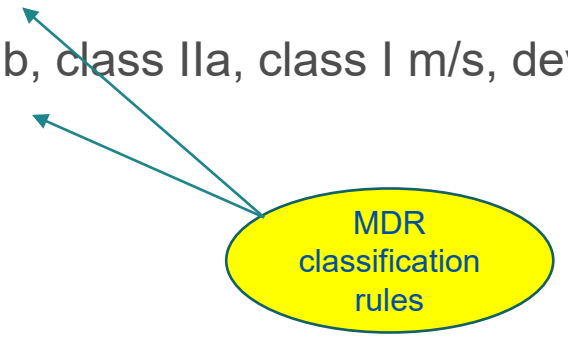
(8) Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions (OJ L 130, 24.4.2020, p. 18).

European Commission

Extension of MDR transitional period

- **Scope ("legacy devices")**
  - Devices covered by MDD/AIMDD certificate issued by NB before 26 May 2021
  - Devices requiring NB involvement for the first time under MDR with MDD Declaration of Conformity drawn up before 26 May 2021 ("*MDD self-declared devices*")

- Staggered **timelines** depending on risk class
  - **31 December 2027** (class III and class IIb implantable, if not excepted, e.g. sutures etc.)
  - **31 December 2028** (other class IIb, class IIa, class I m/s, devices requiring NB involvement for the first time under MDR)



Extension of MDR transitional period

- **Conditions** for extension
  - Continuous compliance with MDD/AIMDD
  - No significant change in design/intended purpose
  - No unacceptable risk to health/safety
  - MDR QMS in place from 26 May 2024
  - Application for conformity assessment of (substitute) device lodged by 26 May 2024
  - Contract MF-NB signed by 26 September 2024

- **Extension of validity of MDD/AIMDD certificates** (*if above conditions are fulfilled*)
  - All MDD/AIMDD certificates valid on 20 March 2023 and not withdrawn
  - Beyond original expiry date until end of transitional period (no update of date on certificate)
  - Also certain certificates that had expired before 20 March 2023, if
    - Contract MF-NB for conformity assessment signed before expiry of certificate *or*
    - Device allowed on the market based on national measures

Extension of MDR transitional period

- **Surveillance** by notified bodies during transitional period
  - no later than 26 September 2024 by MDR notified body
  - concerns only devices covered by a certificate
- Temporary derogation for **class III custom-made implantable** devices
  - MDR QMS certificate required only from 26 May 2026
- **Removal of 'sell-off'** dates in MDR and IVDR
  - devices placed on the market before or during the (extended) transitional period and still in supply chain can be further made available

Extension of MDR transitional period

Effects on manufacturers and devices

- ‘Legacy devices’ can be placed on EU market until 31 Dec. 2027/2028 (according to risk class)
- Also after MDR certification of the device (unless MDD/AIMDD certificate is withdrawn)
- High level of safety
  - PMS/Vigilance requirements of MDR apply since 26 May 2021
  - Surveillance by notified bodies

Extension of MDR transitional period

Documents confirming that device is covered by extended transitional period

- **Manufacturer's Declaration**
  - Common template (see EU Commission website and Q&A)
  - Details on MF, legacy devices, certificates, validity date, MDR Notified Body etc.
- **Notified Body Confirmation Letter** (optional)
  - Common template by NBCG-Med (see EU Commission website and Q&A)
  - List of devices covered by the extension
- **Free Sale Certificate**
  - by National Competent Authorities

Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	
Manufacturer address and contact details	
Single Registration Number (SRN) (if available)	

Authorised Representative name (if applicable)	
Authorised Representative address and contact details	
Single Registration Number (SRN) (if available)	

Notified body name (if applicable)	☐ See attached schedule
Notified body number (if applicable)	☐ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	☐ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	☐ See attached schedule
End date of extended validity/transition period	☐ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

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HPRA CERTIFIED

HPRA

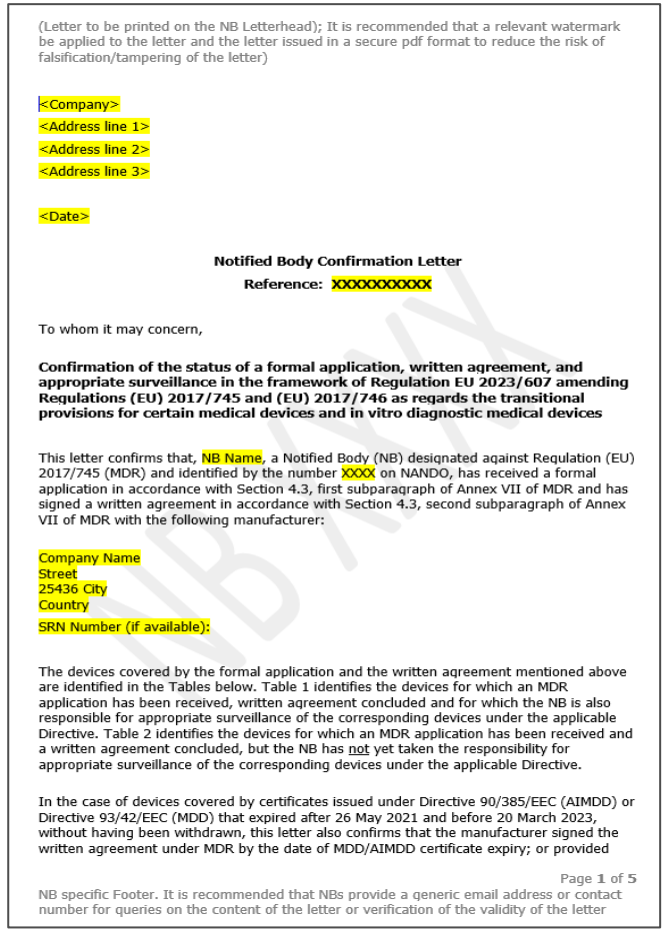
23 July 2014

CERTIFICATE OF FREE SALE

To Whom It May Concern

The Health Products Regulatory Authority hereby certifies that:

1) Renault-Petersen Limited, 6-9 Trinity Street Dublin 2 Ireland is the authorised representative in Ireland for the general medical devices specified in the attached schedule. These devices are manufactured by BIO-CONCEPT CO., LTD. Unit C, No. 26 Huashan Middle Road, XinBei Zone, Changzhou, 213022 Jiangsu, China.
2) The general medical devices specified in the attached schedule are CE marked in accordance with the European Communities (Medical Devices) Regulations, 1994 (which transposed the Medical Devices Directive 93/42/EEC into Irish Law) and may be marketed and sold in Ireland.
3) Exportation of the general medical devices listed in the attached schedule is not prohibited.
4) The granting of this certificate is based on the information available to the Health Products Regulatory Authority on the date of issue of the certificate.



(Letter to be printed on the NB Letterhead); It is recommended that a relevant watermark be applied to the letter and the letter issued in a secure pdf format to reduce the risk of falsification/tampering of the letter)

<Company>
<Address line 1>
<Address line 2>
<Address line 3>

<Date>

Notified Body Confirmation Letter
Reference: XXXXXXXXX

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, NB Name, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number XXXX on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Company Name
Street
25436 City
Country
SRN Number (if available):

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided

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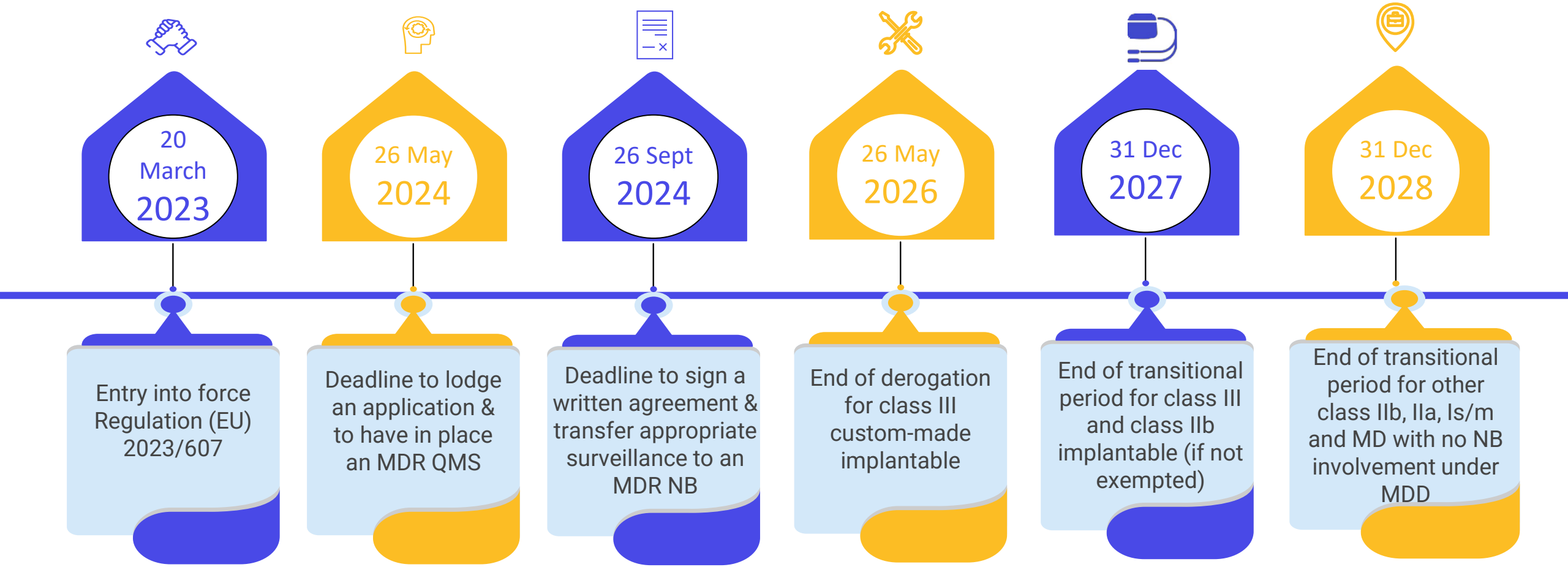
NB specific Footer. It is recommended that NBs provide a generic email address or contact number for queries on the content of the letter or verification of the validity of the letter

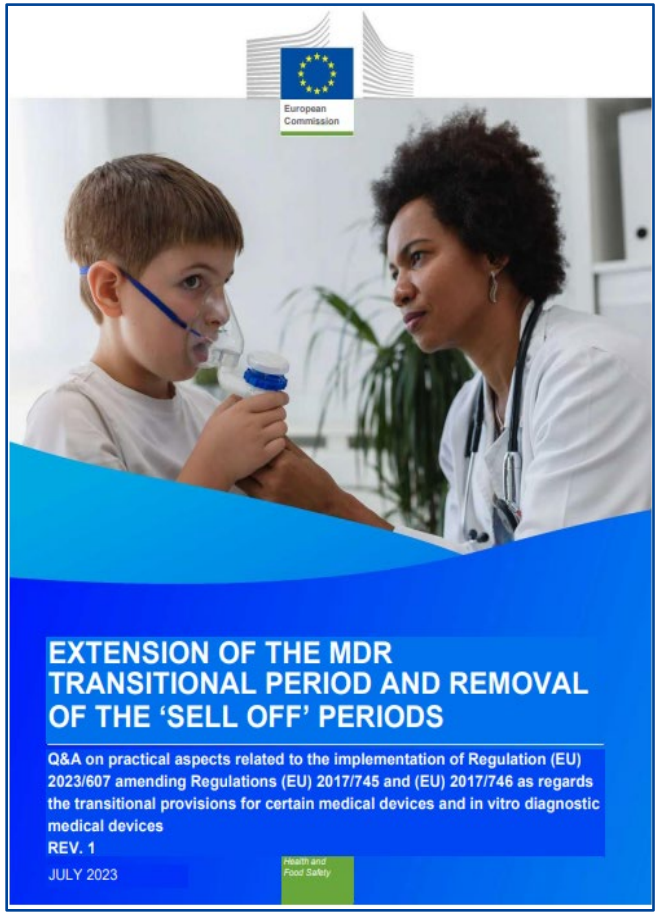
European Commission

Extended MDR transitional period

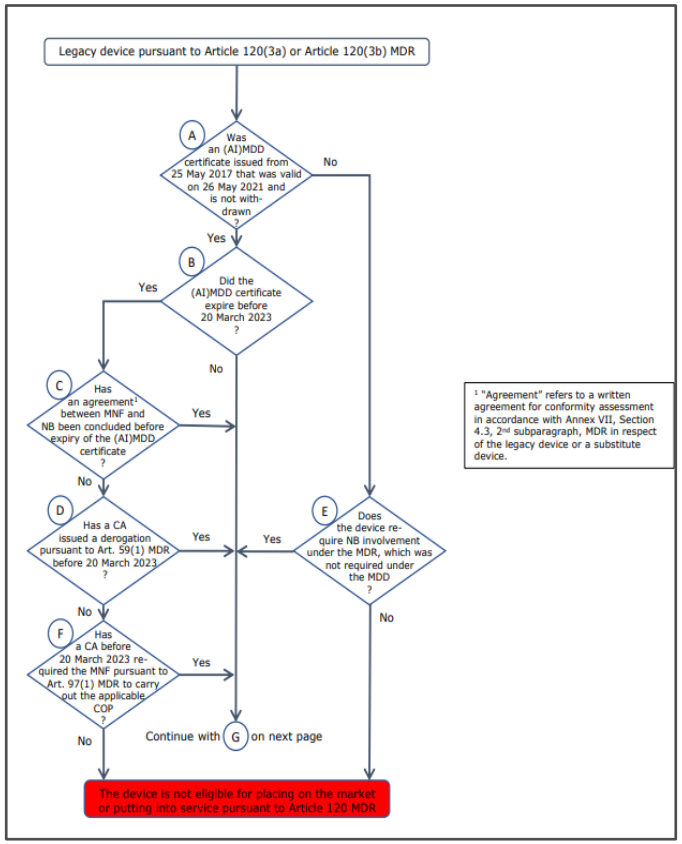


30.4.2024: >23,500 applications

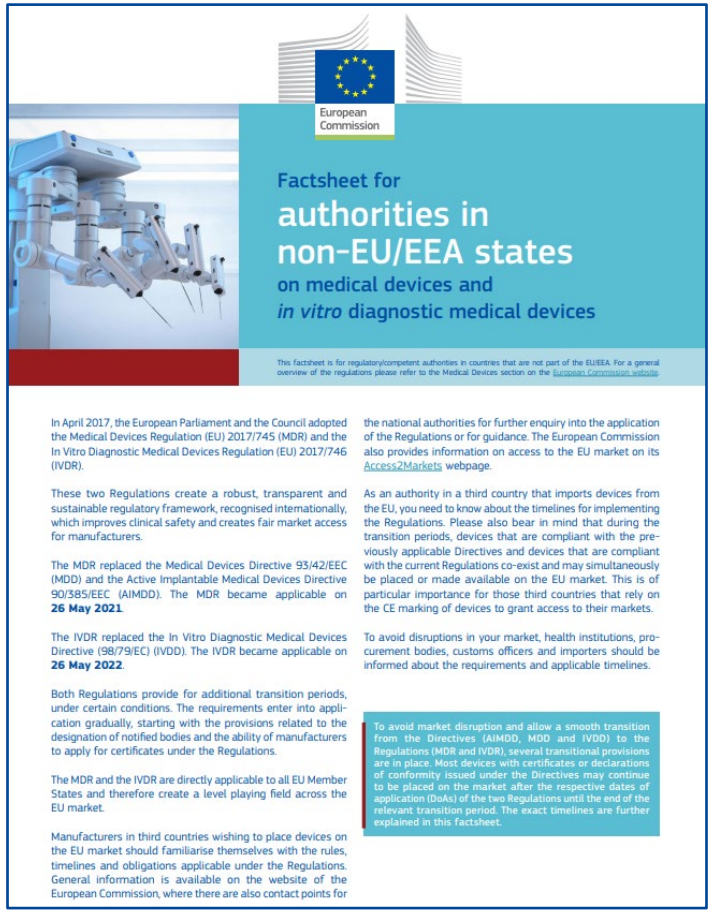
European Commission



mdr_proposal_extension-q-n-a.pdf (europa.eu)



md_devices-art120_flowchart_0.pdf (europa.eu)



MDR-IVDR_FS_third-countries_en (europa.eu)

MDCG guidance documents supporting the transition

- MDCG 2022-14: Transition to the MDR and IVDR - Notified body capacity and availability of medical devices and IVDs (August 2022)
- MDCG 2020-3 Rev.1: Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD (Sept. 2023)
- MDCG 2022-6: Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR (May 2022)
- MDCG 2022-4 Rev.2: Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD (May 2024)
- MDCG 2022-15: Guidance on appropriate surveillance regarding the transitional provisions under Article 110 of the IVDR with regard to devices covered by certificates according to the IVDD (September 2022)
- MDCG 2021-25: Application of MDR requirements to "legacy devices" and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC (October 2021) *under revision*
- MDCG 2022-8: Regulation (EU) 2017/746 - application of IVDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2022 in accordance with Directive 98/79/EC (May 2022)
- MDCG 2024-10: Guidance on clinical evaluation of orphan medical devices (June 2024) *new!*
- ....

Upcoming MDR/IVDR amendment

Regulation (EU) 2024/… of 13 June 2024 amending MDR and IVDR as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices (9 July 2024 expected publication in the OJEU)

1

Ensure availability especially of high-risk in vitro diagnostics (IVDs) by extending transition periods

2

Provide healthcare systems **more time to safeguard patient care** by introducing advance warning of interruption or discontinuation of supply of certain medical devices / IVDs

3

Enhance transparency by enabling a gradual roll-out of the European Database on Medical Devices (EUDAMED)

Extension of IVDR transitional period

- **Scope**
  - Devices covered by IVDD certificate issued by NB before 26 May 2022
  - Devices requiring NB involvement for the first time under IVDR with IVDD Declaration of Conformity drawn up before 26 May 2022 ("*IVDD self-declared devices*")

- Staggered **timelines** depending on risk class
  - **31 December 2027** (devices covered by IVDD certificate and class D devices)
  - **31 December 2028** (class C devices)
  - **31 December 2029** (class B and class A sterile devices)

Extension of IVDR transitional period

- **Conditions** for extension
  - Continuous compliance with IVDD
  - No significant change in design/intended purpose
  - No unacceptable risk to health/safety
  - IVDR QMS in place from 26 May 2025
  - Application for conformity assessment of (substitute) device lodged
    - by 26 May 2025, for devices covered by IVDD certificate and class D devices
    - by 26 May 2026, for class C devices
    - by 26 May 2027, for class B and class A sterile devices
  - Contract MF-NB signed
    - by 26 September 2025, for devices covered by IVDD certificate and class D devices
    - by 26 September 2026, for class C devices
    - by 26 September 2027, for class B and class A sterile devices

Extension of IVDR transitional period

- **Extension of validity of IVDD certificates** (*if above conditions are fulfilled*)
  - All IVDD certificates valid on 9 July 2024 (tbc) and not withdrawn
  - Beyond original expiry date until end of transitional period (no update of date on certificate)
  - Also certain certificates that had expired before 9 July 2024 (tbc), if
    - Contract MF-NB for conformity assessment signed before expiry of certificate *or*
    - Device allowed on the market based on national measures
- **Surveillance** by notified bodies during transitional period
  - by IVDR notified body at the latest from the date when contract MF-NB must be signed (i.e. 26 September 2025/2026/2027);
  - concerns only devices covered by a certificate

Extension of IVDR transitional period

Effects on manufacturers and devices

- ‘Legacy devices’ can be placed on EU market until 31 Dec. 2027/2028/2029 (according to risk class)
- Also after IVDR certification of the device (unless IVDD certificate is withdrawn)
- High level of safety
  - PMS/Vigilance requirements of IVDR apply since 26 May 2022
  - Surveillance by notified bodies

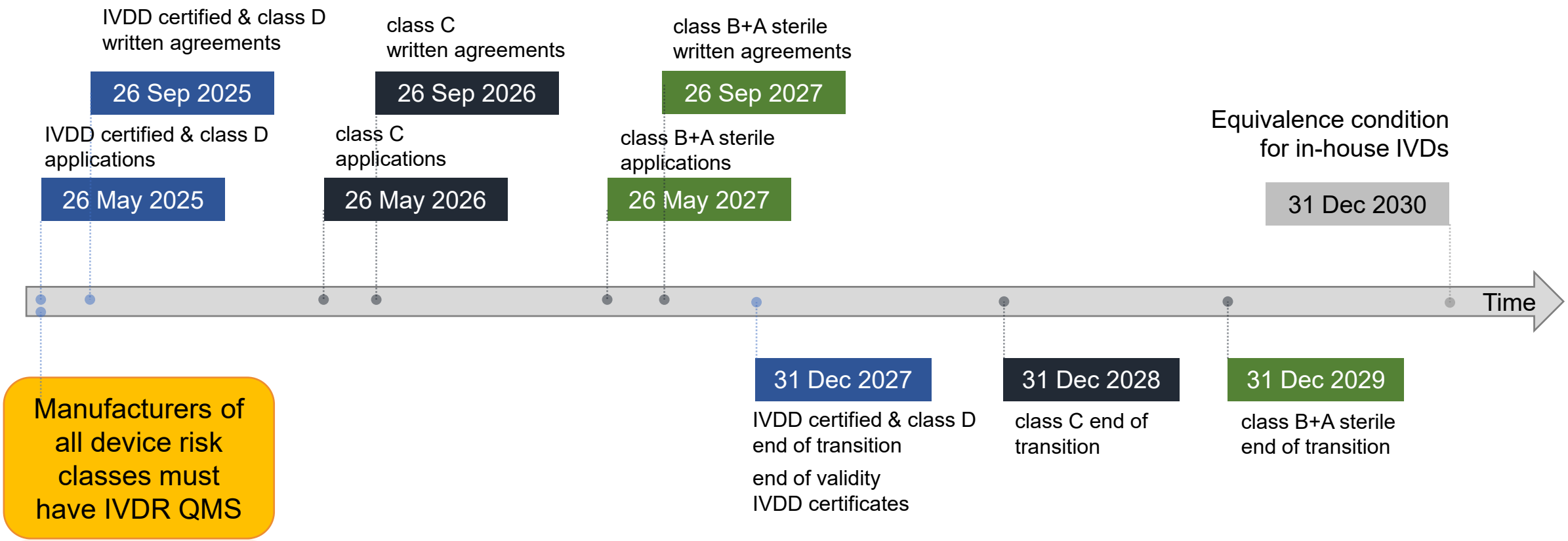
Extension of IVDR transitional period

Documents confirming that device is covered by extended transitional period (same as for MDR)

- **Manufacturer's Declaration**
  - Common template
  - Details on MF, legacy devices, certificates, validity date, MDR Notified Body etc.
- **Notified Body Confirmation Letter** (optional)
  - Common template by NBCG-Med
  - List of devices covered by the extension
- **Free Sale Certificate**
  - by National Competent Authorities

Coming soon

IVDR – Transitional periods

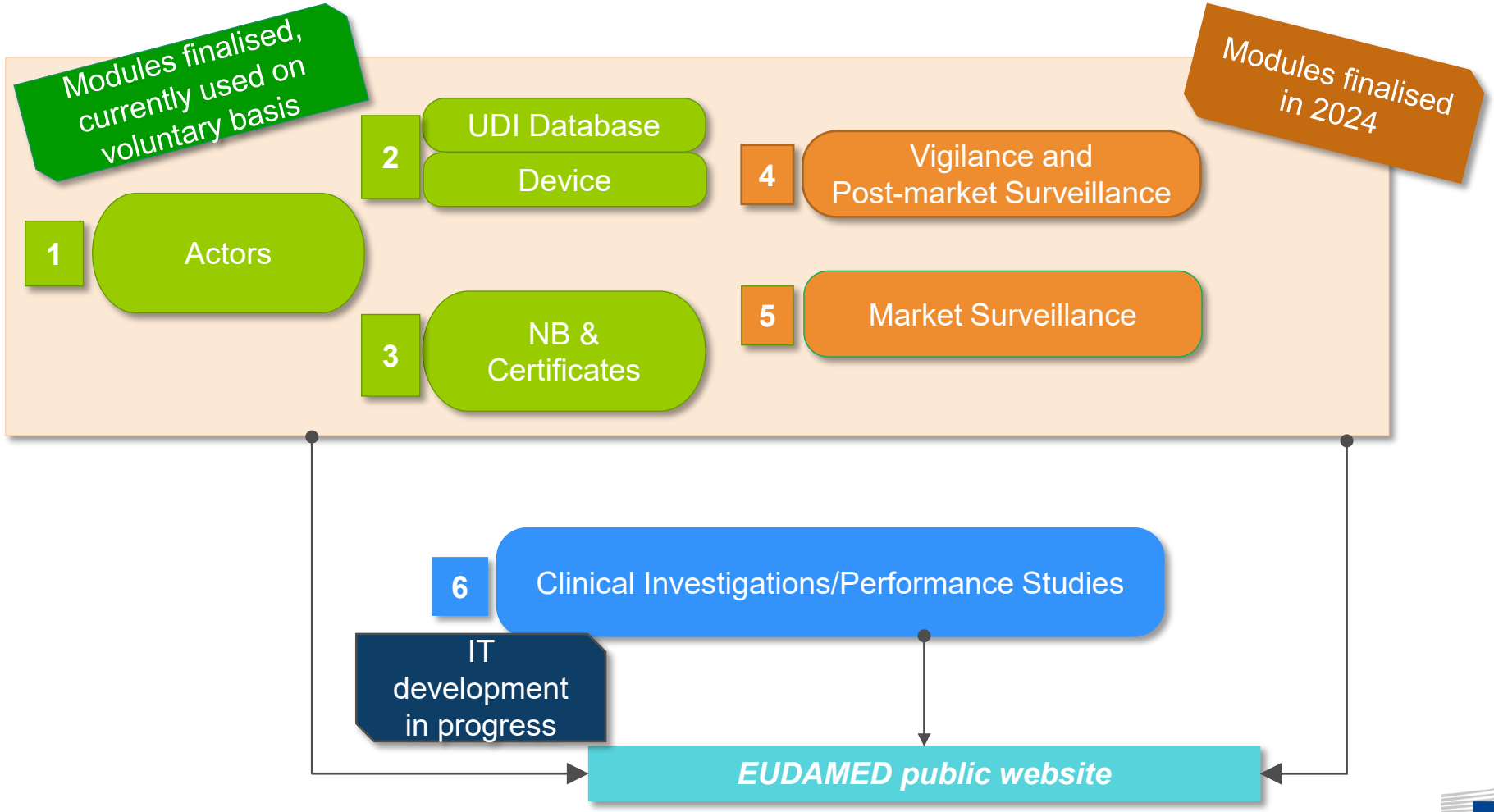


European Commission

Prior information about discontinuation or interruption of supply (new Article 10a MDR/IVDR)

- *Who?*
  - Manufacturers
- *What?*
  - Discontinuation or interruption of supply of MD or IVD
  - Risk of serious harm to patients or public health
- *When?*
  - 6 months in advance
- *To whom?*
  - NCA where manufacturer/AR is established (+information exchange between NCAs)
  - Economic operators (e.g. importer, distributor) or hospitals/healthcare professionals

Gradual roll-out of EUDAMED

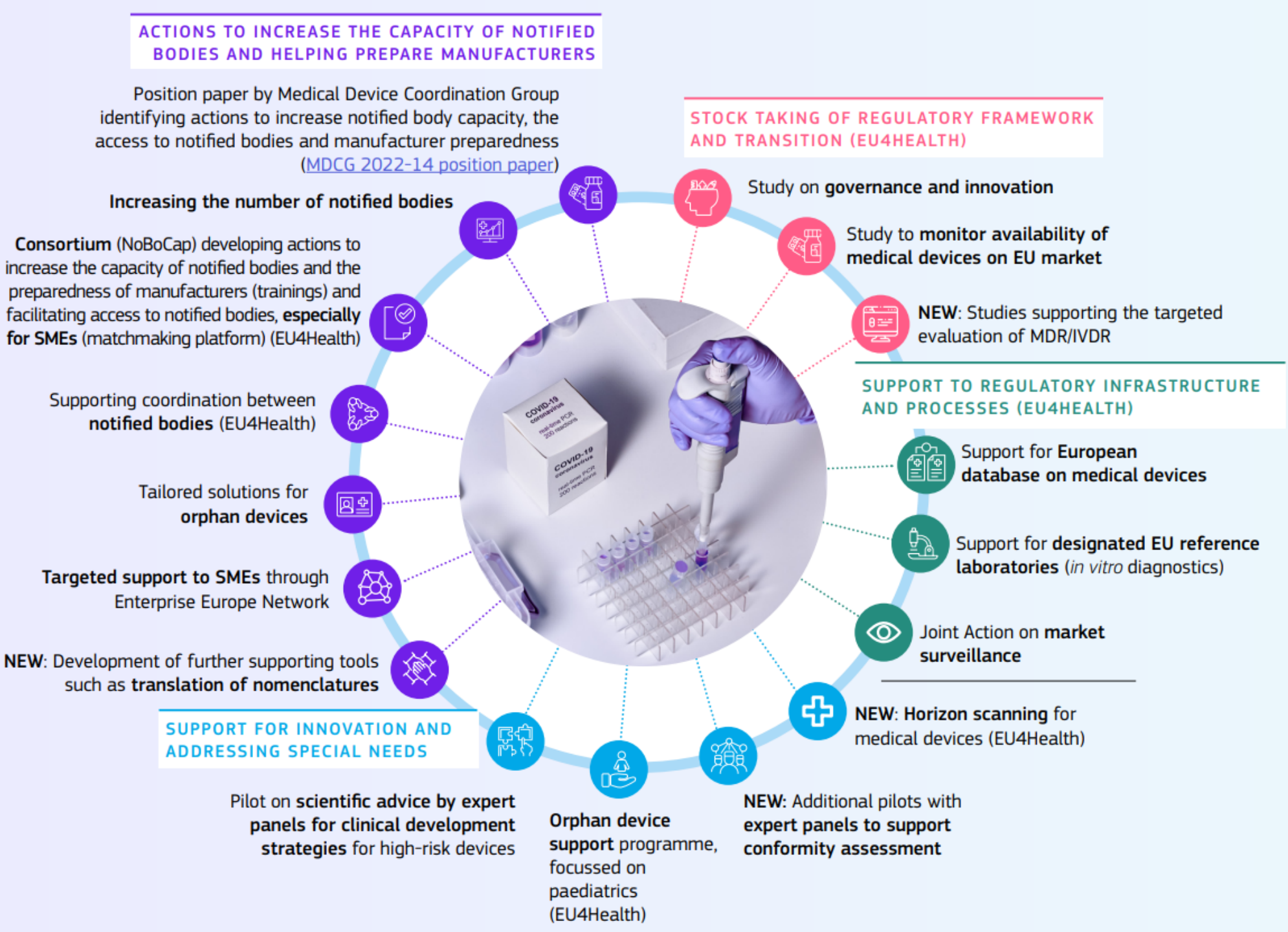


European Commission

Gradual roll-out of EUDAMED

- Enables mandatory use of a EUDAMED module 6 months after publication of EC notice confirming module's functionality
- **One registration throughout EU**
- Additional time for MF and NB to migrate device data and certificate information for certain devices from national databases to EUDAMED
- Coordinated assessment of applications for clinical investigations or performance studies only when EUDAMED CI/PS module will become mandatory

Non-legislative measures



Targeted evaluation of MDR/IVDR

- Assessment of underlying causes of remaining challenges
  - Availability of devices needed for patient care
  - Costs, predictability and administrative burden, especially for SME
  - Governance
  - Innovation in EU

Early and targeted evaluation of MDR/IVDR

Targeted evaluation of MDR/IVDR - timeline

EU rules on medical devices and in vitro diagnostics – targeted evaluation (europa.eu)

European Commission

Thank you!

Relevant contacts:

Websites:

- European Commission
- Directorate-General for Health and Food Safety (DG SANTE)
- Unit D.3 Medical Devices

Email address:

- SANTE-MED-DEV[at]ec.europa.eu
- SANTE-MD-INTERNATIONAL[at]ec.europa.eu

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