IMDRF International Medical Device Regulators Forum | 26th Session

Regulatory update from the EU

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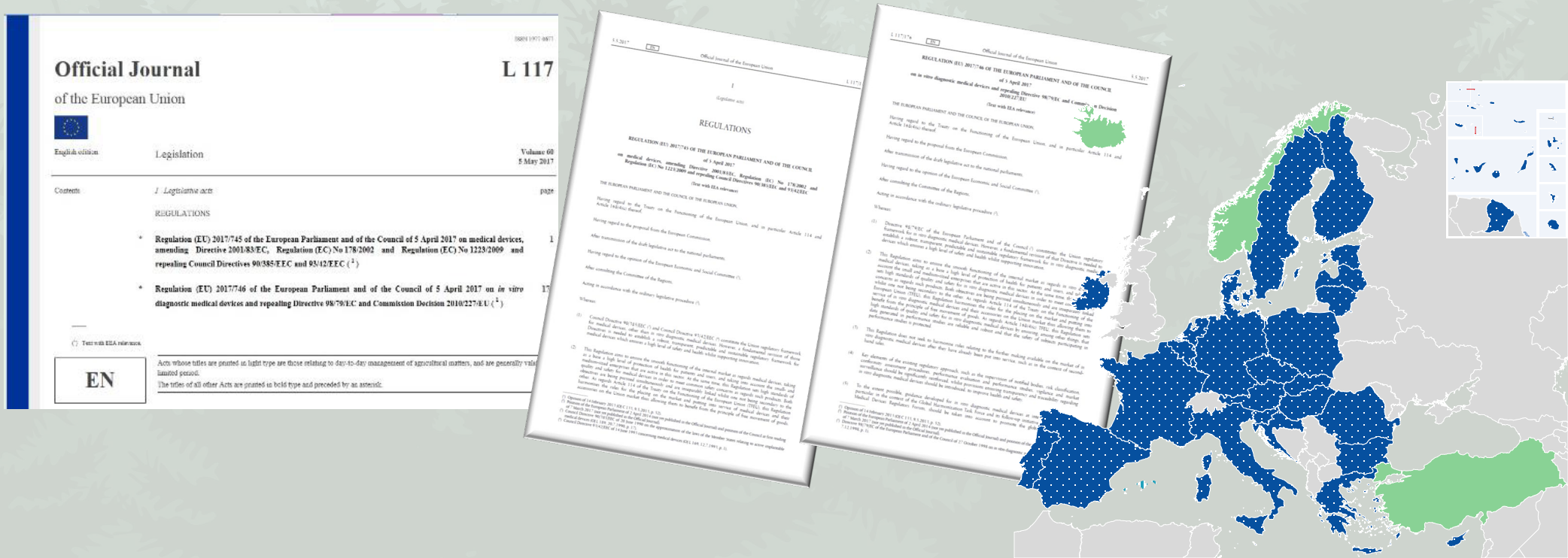
European Commission

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’



Objectives

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

Achievements

50 MDR notified bodies (12 applications ongoing)

~8,000 MDR certificates issued

13 IVDR notified bodies (8 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

MDR transitional period

20 March 2023
Entry into force Regulation (EU) 2023/607

26 May 2024
Deadline to lodge an application & to have in place an MDR QMS

26 Sept 2024
Deadline to sign a written agreement & transfer appropriate surveillance to an MDR NB

26 May 2026
End of derogation for class III custom-made implantable

31 Dec 2027
End of transitional period for class III and class IIb implantable (if not exempted)

31 Dec 2028
End of transitional period for other class IIb, IIa, Is/m and MD with no NB involvement under MDD

30.4.2024: >23,500 applications

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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

3

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

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Extension of IVDR transition periods - Conditions

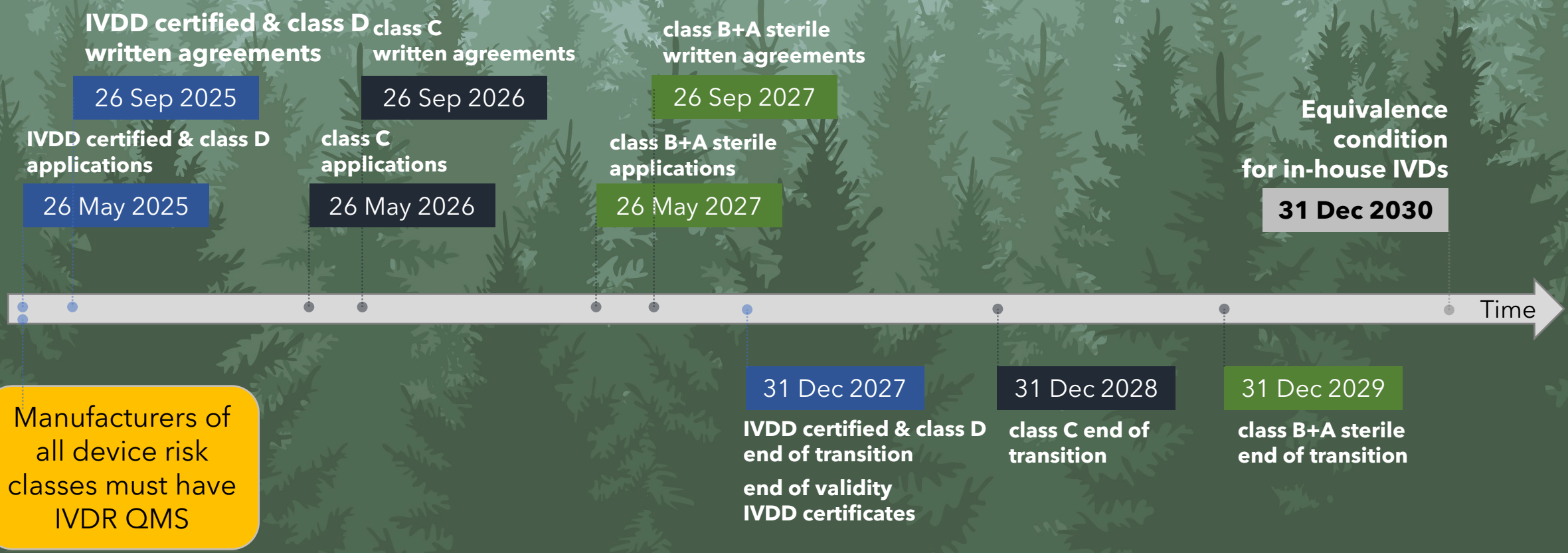
1

- Continuous compliance with IVD Directive
- No significant changes
- No unacceptable risk to health/safety
- IVDR compliant QMS in place by 26 May 2025
- applications lodged and written agreements with notified bodies signed by certain staggered deadlines (depending on risk class)

Extension of validity of IVD Directive certificates and/or devices can continue be placed on the market

IVDR – Transitional periods

1



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

2

- ***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

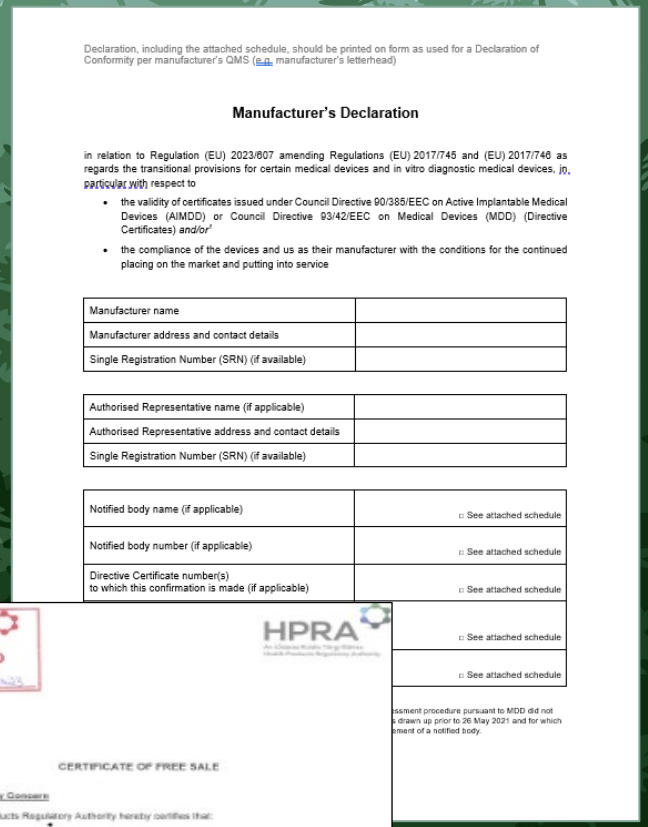
3

- 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

MDR and IVDR transitional period documents

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

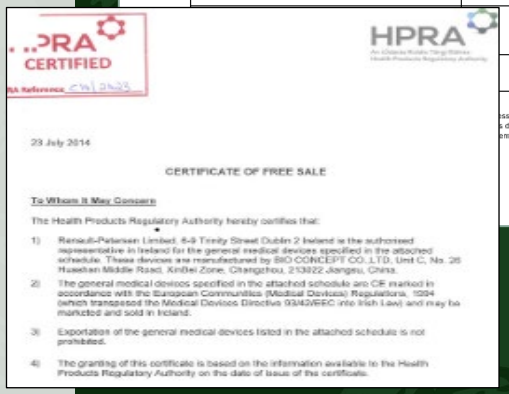
in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- 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
	☐ See attached schedule
	☐ See attached schedule



HPRA CERTIFIED

HPRA

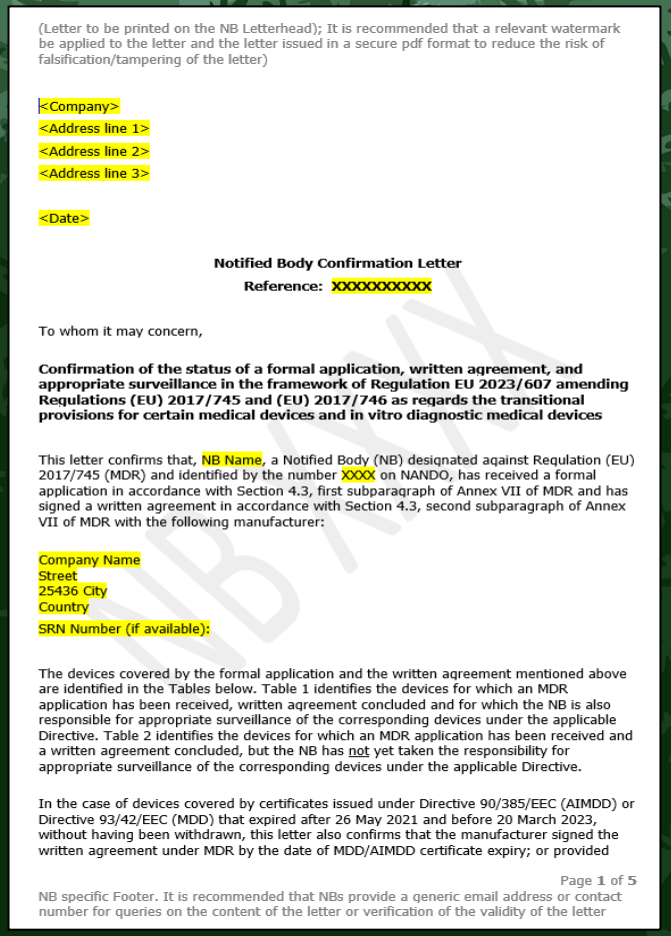
23 July 2014

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 SIO CONCEPT CO. LTD, Unit C, No. 26 Huaxian 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: XXXXXXXXXX

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

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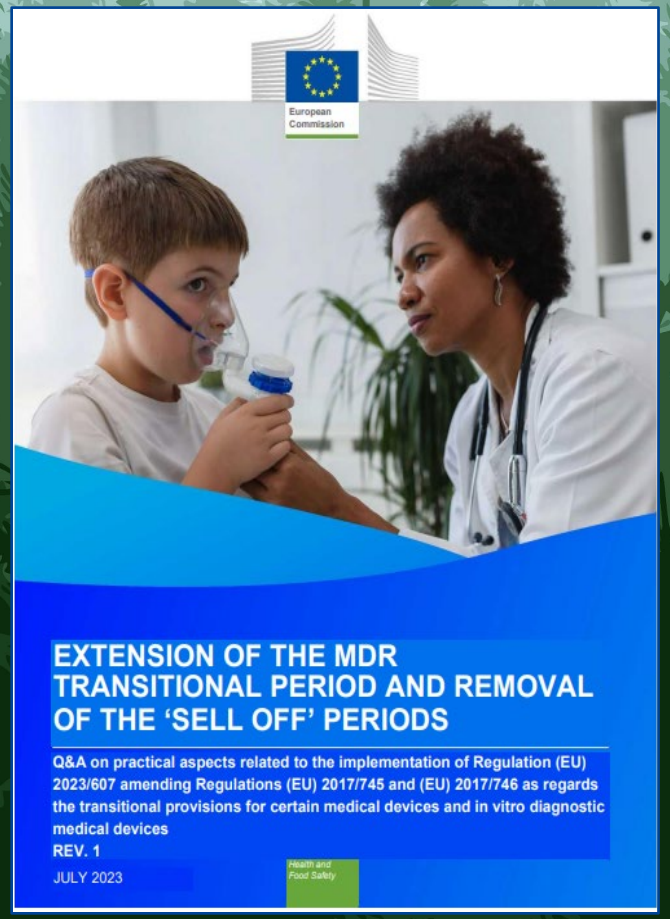
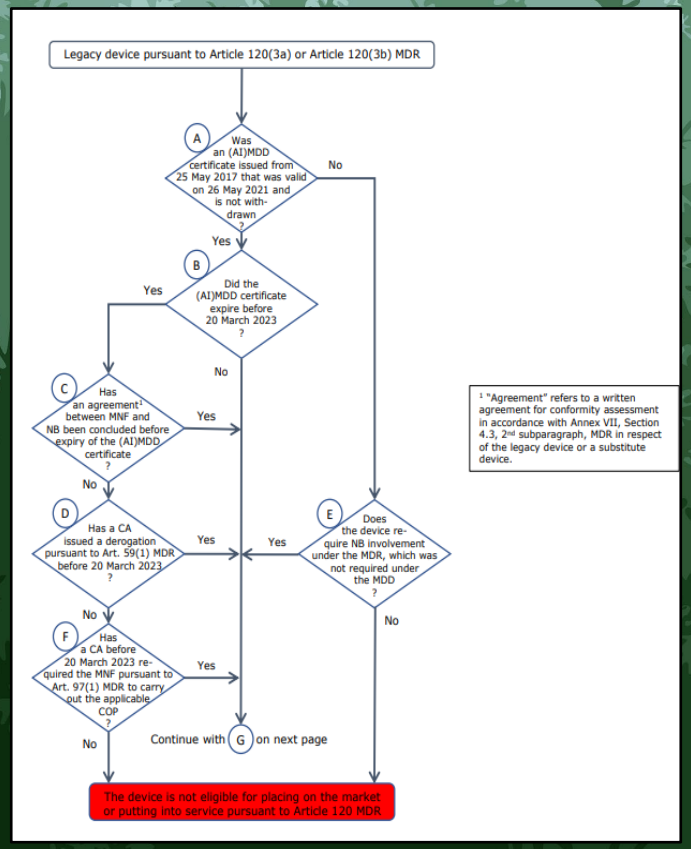
Guidance for all actors and global partners



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)

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Webinar for international partners

Presentation: https://shorturl.at/8ylYd

European Commission

Webinar: https://vimeo.com/981305833

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

Information session for international regulators and stakeholders

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Guidance under development

1. Documents confirming that device is covered by extended transitional period (same as for MDR)
2. Article 10 (a) about discontinuation or interruption of supply
3. Eudamed requirements and registration obligations

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Orphan medical devices

MDCG 2024-10: Clinical evaluation of orphan medical devices

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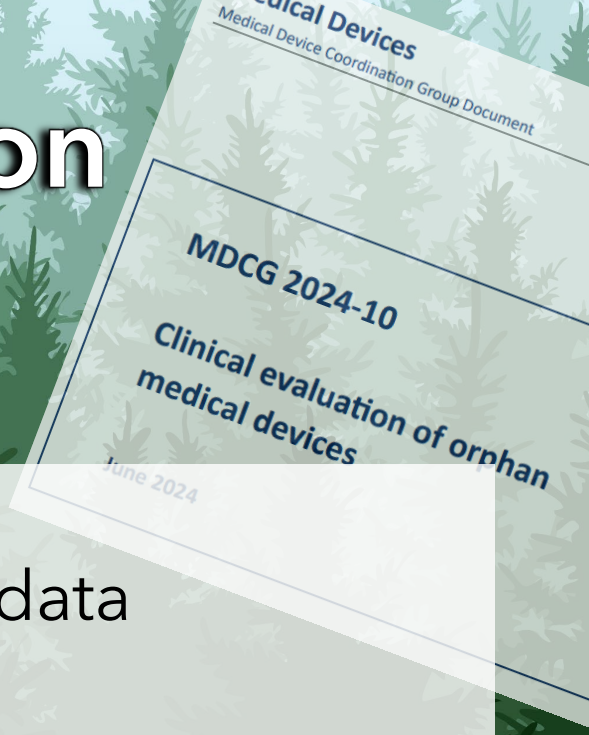
MDCG 2024-10 Clinical evaluation of orphan medical devices



- Pre-market clinical data for orphan devices
  - Acceptability of limitations in pre-market clinical data
  - Considerations for CIs for OD
  - Extrapolation of clinical data to orphan indications
- PMCF for orphan devices
- MFR & NB activities and responsibilities
- Expert panels: advice on OD status and clinical evidence

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Under development

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Electronic instructions for use for professional use medical devices

1 August 2024 - 11 October 2024

https://ec.europa.eu/eusurvey/runner/Survey_eIFUs_medicaldevices_2024

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AI-enabled medical devices

Regulated under MDR/IVDR and the AI Act

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Implementation

- AI Board – 1st official meeting on 10 September 2024
- Establish of a joint governance system between MDCG and the AI Board
- Nomination of AI experts (with knowledge of MDs) until end of September
- First physical joint meeting – December 2024 MDCG New Technologies WG

Priorities:

❑ FAQ on interplay between MDR/IVDR and the AI Act

❑ Implementing Act on the establishment of Regulatory Sandboxes

Targeted Evaluation of MDR / IVDR

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Our overall timeline

Q4 2023	Q1-Q3 2024	Q3-Q4 2024	Q4 2024	2024/2025	Q2-Q4 2025
Scoping phase	Building the foundations of the Evaluation (intervention logic, Evaluation questions)	Data mapping & consultation strategy	Call for evidence & public consultation	Data collection and analysis	Scrutiny & Validation & Adoption & Publication

This is where we are now

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THANK YOU

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