



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'

Official Journal
of the European Union

English edition Legislation Volume 60
5 May 2017

Contents	J. Legislative acts	page
	REGULATIONS	
	* 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 ⁽¹⁾	1
	* Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on <i>in vitro</i> diagnostic medical devices and repealing Directive 98/78/EC and Commission Decision 2010/227/EU ⁽²⁾	17

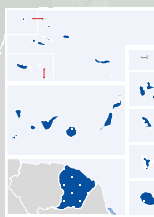
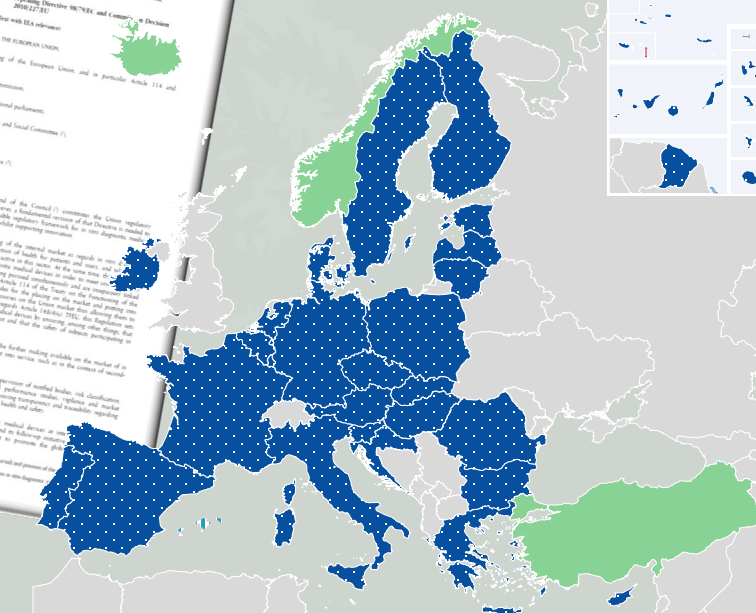
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Official Journal of the European Union

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

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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 98/78/EC and Commission Decision 2010/227/EU



Objectives

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

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

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

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



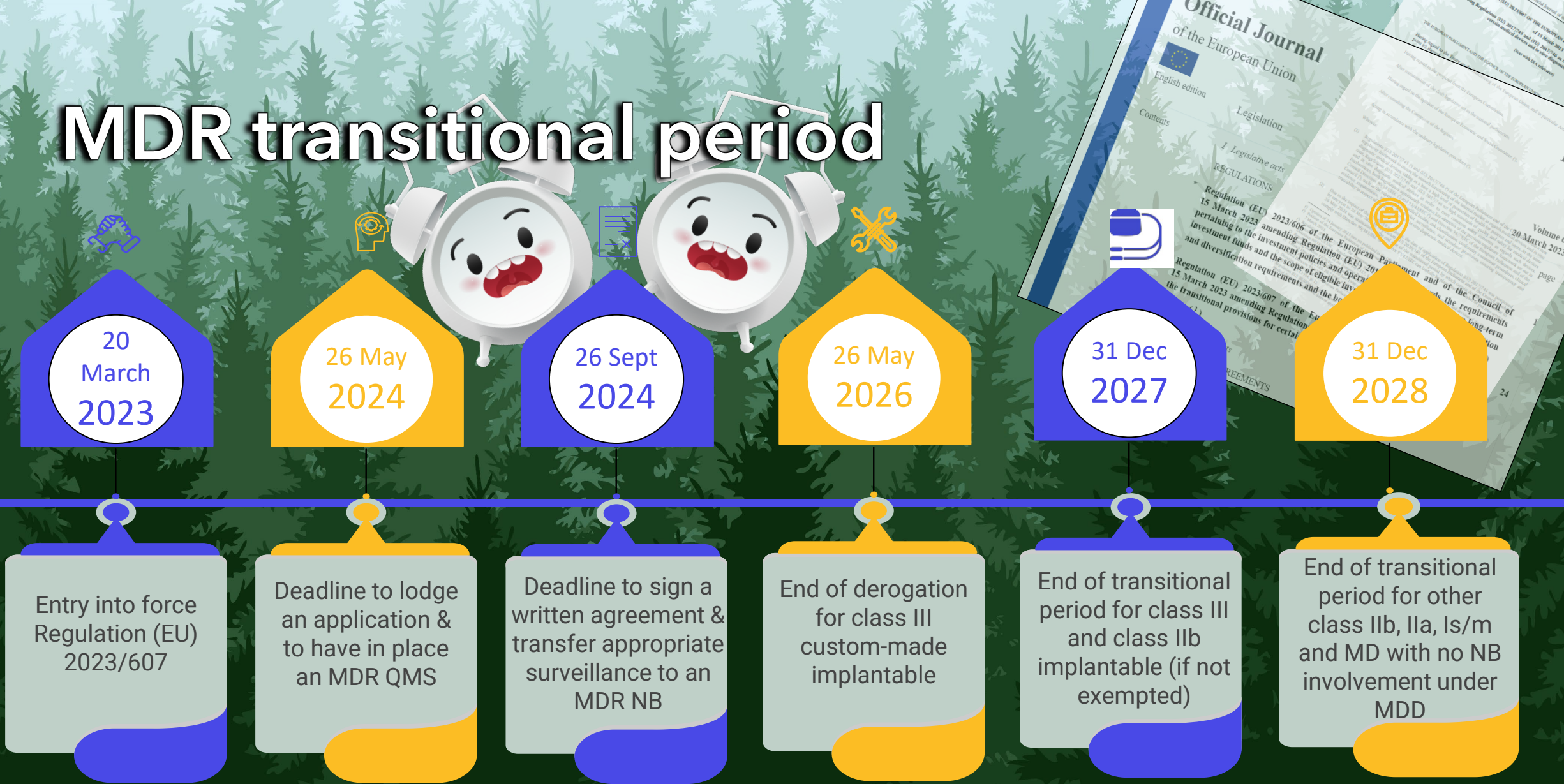
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MDR transitional period



30.4.2024:
>23,500
applications

 **U.S. FOOD & DRUG
ADMINISTRATION**

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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



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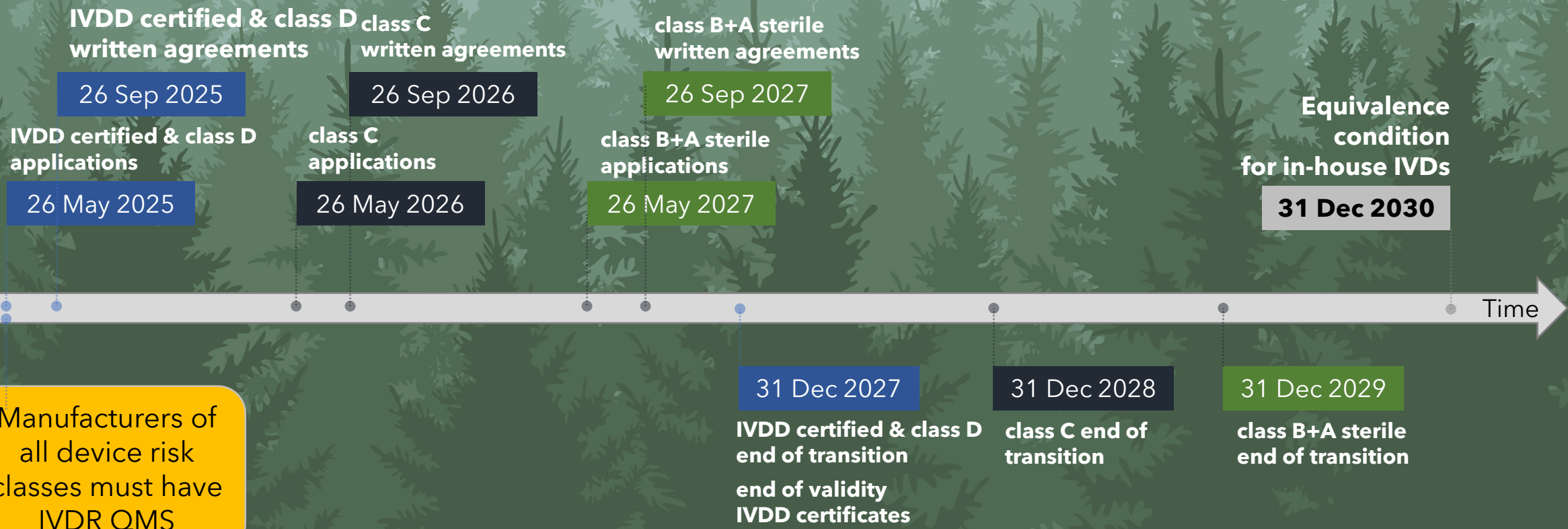


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IVDR - Transitional periods

1



Manufacturers of all device risk classes must have IVDR QMS



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

Q&A
work in
progress

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



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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
- 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)	<input type="checkbox"/> See attached schedule
Notified body number (if applicable)	<input type="checkbox"/> See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	<input type="checkbox"/> See attached schedule

	<input type="checkbox"/> See attached schedule
	<input type="checkbox"/> See attached schedule




23 July 2014

CERTIFICATE OF FREE SALE

To Whom It May Concern

The Health Products Regulatory Authority hereby certifies that:

- 1) Renault-Palonen Limited, 8-9 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 SHO CONCEPT CO., LTD, Unit C, No. 28 Huaibei Middle Road, Xuhai 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, 2004 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,

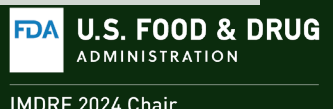
Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

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



Guidance for all actors and global partners



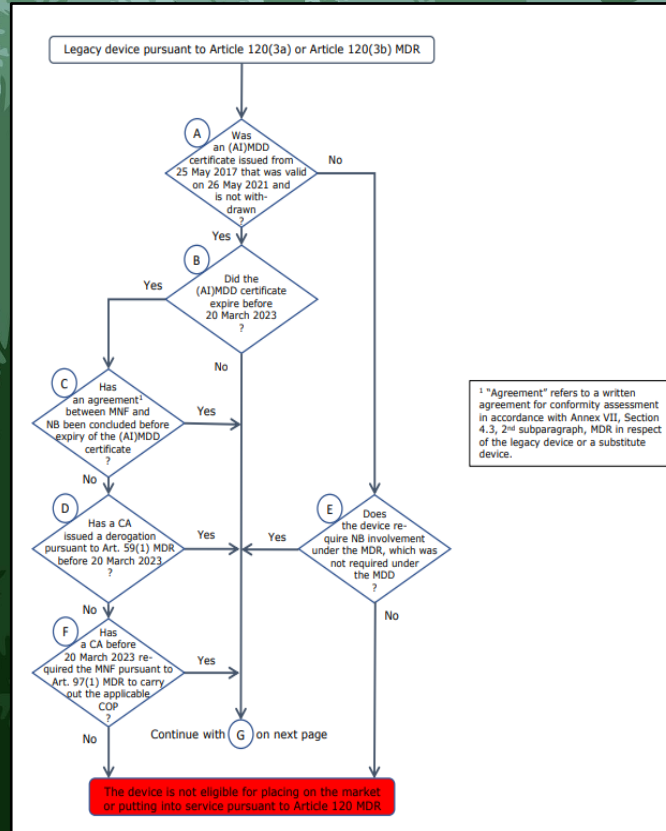
EXTENSION OF THE MDR TRANSITIONAL PERIOD AND REMOVAL OF THE 'SELL OFF' PERIODS

Q&A on practical aspects related to the implementation 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

REV. 1
JULY 2023

Health and Food Safety

[mdr_proposal_extension-q-n-a.pdf \(europa.eu\)](#)



[md_devices-art120_flowchart_0.pdf \(europa.eu\)](#)



Factsheet for authorities in non-EU/EEA states on medical devices and in vitro diagnostic medical devices

The factsheet is for regulatory/competent authorities in countries that are not part of the EUMEA. For a general overview of the regulations please refer to the Medical Devices section on the [European Commission website](#).

In April 2017, the European Parliament and the Council adopted the Medical Devices Regulation (EU) 2017/745 (MDR) and the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR).

These two Regulations create a robust, transparent and sustainable regulatory framework, recognised internationally, which improves clinical safety and creates fair market access for manufacturers.

The MDR replaced the Medical Devices Directive 93/42/EEC (MDD) and the Active Implantable Medical Devices Directive 90/385/EEC (AIMDD). The MDR became applicable on **26 May 2021**.

The IVDR replaced the In Vitro Diagnostic Medical Devices Directive (98/79/EC) (IVDD). The IVDR became applicable on **26 May 2022**.

Both Regulations provide for additional transition periods, under certain conditions. The requirements enter into application gradually, starting with the provisions related to the designation of notified bodies and the ability of manufacturers to apply for certificates under the Regulations.

The MDR and the IVDR are directly applicable to all EU Member States and therefore create a level playing field across the EU market.

Manufacturers in third countries wishing to place devices on the EU market should familiarise themselves with the rules, timelines and obligations applicable under the Regulations. General information is available on the website of the European Commission, where there are also contact points for the national authorities for further enquiry into the application of the Regulations or for guidance. The European Commission also provides information on access to the EU market on its [Access2Markets](#) webpage.

As an authority in a third country that imports devices from the EU, you need to know about the timelines for implementing the Regulations. Please also bear in mind that during the transition periods, devices that are compliant with the previously applicable Directives and devices that are compliant with the current Regulations co-exist and may simultaneously be placed or made available on the EU market. This is of particular importance for those third countries that rely on the CE marking of devices to grant access to their markets.

To avoid disruptions in your market, health institutions, procurement bodies, customs officers and importers should be informed about the requirements and applicable timelines.

To avoid market disruption and allow a smooth transition from the Directives (AIMDD, MDD and IVDD) to the Regulations (MDR and IVDR), several transitional provisions are in place. Most devices with certificates or declarations of conformity issued under the Directives may continue to be placed on the market after the respective dates of application (DoA) of the two Regulations until the end of the relevant transition period. The exact timelines are further explained in this factsheet.

[MDR-IVDR FS third-countries en \(europa.eu\)](#)



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International Medical Device Regulators Forum

Webinar for international partners

Presentation: <https://shorturl.at/8ylyd>



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

This is where we are now



Call for evidence & public consultation



Data collection and analysis



Scrutiny & Validation & Adoption & Publication

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