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# MDR extension period

Your practical timeline map

**Regulation 2023/607**

# Which medical devices benefit from the extension?

## Only manufacturers of devices actively transitioning to the MDR can benefit of the additional "grace period".

**No extended transition**

- Class I medical devices not requiring NB involvement under MDR (i.e., non-sterile, no measuring function, not reusable surgical instruments).
- Custom-made devices, except for class III custom-made implantable devices.
- "New" devices, i.e., devices not previously CE marked (MDD/AIMDD).

**Extended transition**

- **Legacy medical devices** that did not require NB involvement under MDD/AIMDD, but do so under MDR (e.g., class Is, Im, Ir and certain SaMD). [1]
- **Legacy medical devices** covered by an MDD/AIMDD certificate issued between 25 May 2017 and 26 May 2021 and valid on 26 May 2021. [2]
- **Class III custom-made implantable devices.** [3]

1: This only applies to devices with DoC before 26 May 2021 and if certain conditions set out in Regulation 2023/607 are met
2: The extended deadline will depend on the device risk class and only applies if certain conditions set out in Regulation 2023/607 are met
3: This only applies if a formal NB application was lodged before 26 May 2024 and a written agreement was signed before 26 September 2024

# What are the new timelines?

**2021 May 26**

MDR date of application for
- Class I medical devices / custom-made devices that do not require the involvement of a NB under MDR
- Devices not previously covered by a certificate or declaration of conformity issued under the MDD/AIMDD

**2024 May 26**

- Deadline to apply for MDR conformity assessment and develop MDR-compliant QMS
- Marks the end of transition period for all legacy devices that fail to meet the conditions to benefit from th extension period

**2024 September 26**

Deadline to establish a written agreement with and transfer surveillance to an MDR designated NB

**2026 May 26**

Marks the end of the transition period for all Class III custom-made implantable devices

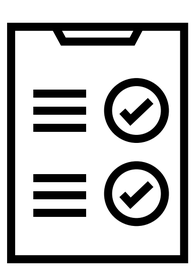
**2027 December 31**

Marks the end of the transition period for Class III and Class IIb implantable devices

**2028 December 31**

Marks the end of the transition period for class IIa, rest of IIb, class I sterile and/or measuring devices and any other devices that require a NB for the first time under MDR

# Which conditions set out in Regulation (EU) 2023/607 are to be met?

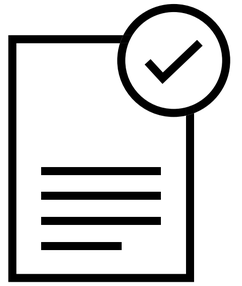


MDD/AIMDD compliance

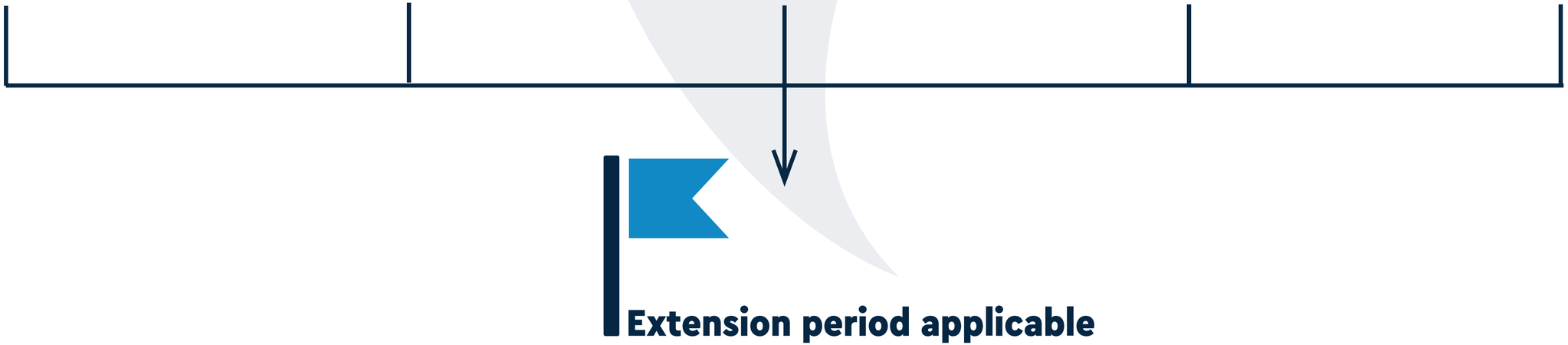
No significant design/intended purpose changes

No unacceptable risk

Application to NB for MDR conformity assessment before 26 May 2024



QMS MDR Art 10(9) compliant by 26 May 2024



# Which conditions set out in Regulation (EU) 2023/607 are to be met?

**If MDD/AIMDD certificate expired before 20 March 2023 (valid on 26 May 2021)**

- MDD/AIMDD compliance
- No significant design/intended purpose changes
- No unacceptable risk
- Application to NB for MDR conformity assessment before 26 May 2024
- QMS MDR Art 10(9) compliant by 26 May 2024
- Art 59(1) **OR** Art 97(1) MDR derogation

**Extension period applicable**

# Which aspects shall a MDR compliant QMS address?

Regulatory Compliance Strategy

Identification of applicable GSPRs and options to address them

Management Responsibilities

Management of resources (e.g., suppliers)

Risk Management procedures in place

Clinical evaluation process

Product planning, design, development, production and service provision


Verification of UDI assignments

Implementation and maintenance of PMS system

Communication with Competent Authorities, NBs, economic operators, customers and other stakeholders

Serious incidents and FSCAs reporting

Management of CAPAs

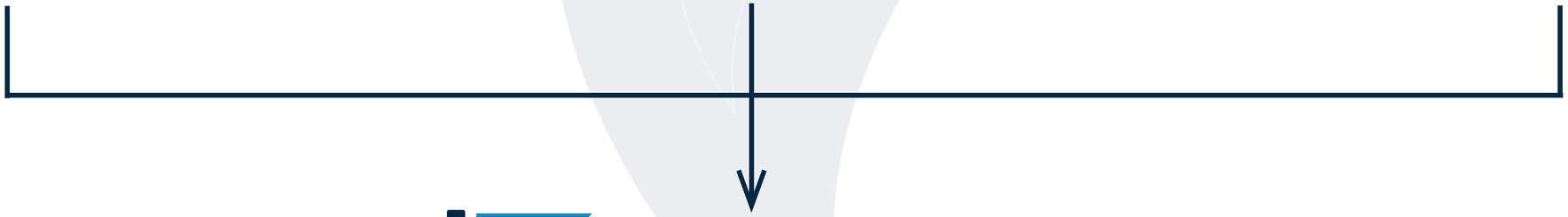
Monitoring and management of output, data analysis and product improvement

# How can the manufacturer demonstrate to be eligible for the extension of the transitional period?

**Manufacturer Self-declaration**
confirming that the conditions for the extension are fulfilled, stating the end date of the transition period.

**Confirmation letter**
by NB stating the receipt of the manufacturer's application for conformity assessment and the conclusion of a written agreement

**Copy of the relevant documents**
to demonstrate application for conformity assessment and concluded written agreement



**Manufacturer eligible for the extension of the transitional period**

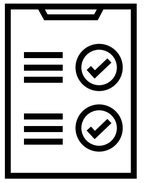
# Manufacturer's Declaration in relation to Regulation (EU) 2023/607

**A self-declaration template has been released by MedTech Europe, including:**

**Status of the Directive Certificate(s)**

**If the device has been upclassified: planned activities**

**QMS status**



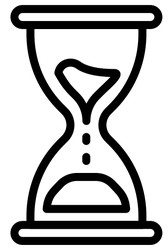
**Article 120(3c) MDR requirements**

## Schedule of Devices

- Device(s) identification (e.g., name, family/group name, model, catalogue number)
- Directive Certificate number(s) – Original expiry date
- NB that issued the Directive Certificate – NB for MDR application
- End date of extended validity / transition period
- Substitute Device(s) (i.e., device with changes in design or intended purpose, meant to replace the legacy device)

# What the cancel of sell-off period means?

Under Art.120(4) MDR a timeline up to 27 May 2024 was set for devices with valid MDD/AIMDD certificates (not transitioned to MDR) to be available in the EU market, including



- all devices still in the supply chain and
- all devices that had not reached the final users and distributors by then

To prevent the projected medical device shortages on the EU market, Regulation (EU) 2023/607 removed this sell-off period

All devices placed on the market in accordance with the MDD/AIMDD can continue to be made available without any limitation in time (only by the device's shelf-life /expiry date)
**UNTIL STOCK DEPLETION!**

# Extension period – third countries accepting CE certificate

**MedDO modifications to implement updated EU timelines in Switzerland. Until then, devices with a valid certificate according to MDR will be accepted.**

**2023** Autumn

**2027** December 30

**2028** June 30

**2030** June 30

**EU MDR new transition periods automatically apply for the Northen Ireland market.**

**Class III and IIb implantable with valid MDD extended certificate**

**Class IIa, IIb with a valid MDD/AIMDD certificate and upclassified Class I and Class Is/Ir/Im with a valid MDD self-declaration**

**All devices with MDR certificate (incl. class I MDR self- declaration)**

**Custom made devices with MDD/AIMDD certificate**

# What medical device manufacturers should do?

## Contact Evnia

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## Move forward with MDR certification

## Ensure that the EU market is not deprived from innovative medical devices