



● Time for your MDR application is now

Be prepared for May 2024 deadline

What happened?

On 20 March 2023, the Regulation (EU) 2023/607 amending the MDR and IVDR was published in the Official Journal of the European Union (OJEU) with immediate effect. The objective of the Amending Regulation is to address the projected imminent risks of shortages of medical devices in EU due to the slower than anticipated transition from the Medical Device Directives to MDR and IVDR.



By Royal Charter



What are the implications?

The Amending Regulation extends the MDR transition timelines while also recognising as valid previously issued MDD, AIMDD Certificates for the duration of those longer transition timelines.

This allows manufacturers to continue placing their devices on the market based on compliance with the Directives while they continue the transition of their devices to the MDR.



Key elements of Amending Regulation (EU) 2023/607

Case 1:

I do not intend to transition my legacy device to the MDR and my Directive Certificate was valid at the time of the publication of the Amending Regulation (EU) 2023/607

Manufacturers **holding Directives Certificates** that have been issued from 25 May 2017, **that were still valid on 26 May 2021**, that have not been withdrawn afterwards and **that were still valid at the time of publication of Regulation (EU) 2023/607** are allowed to continue placing on the market legacy devices until **26 May 2024**, if the below conditions are met:

- The device must continue to comply with the applicable Directive
- No significant changes in design or intended purpose of the device are allowed
- The device does not present an unacceptable risk for patients' health and safety

Appropriate Surveillance must be guaranteed for the legacy devices.

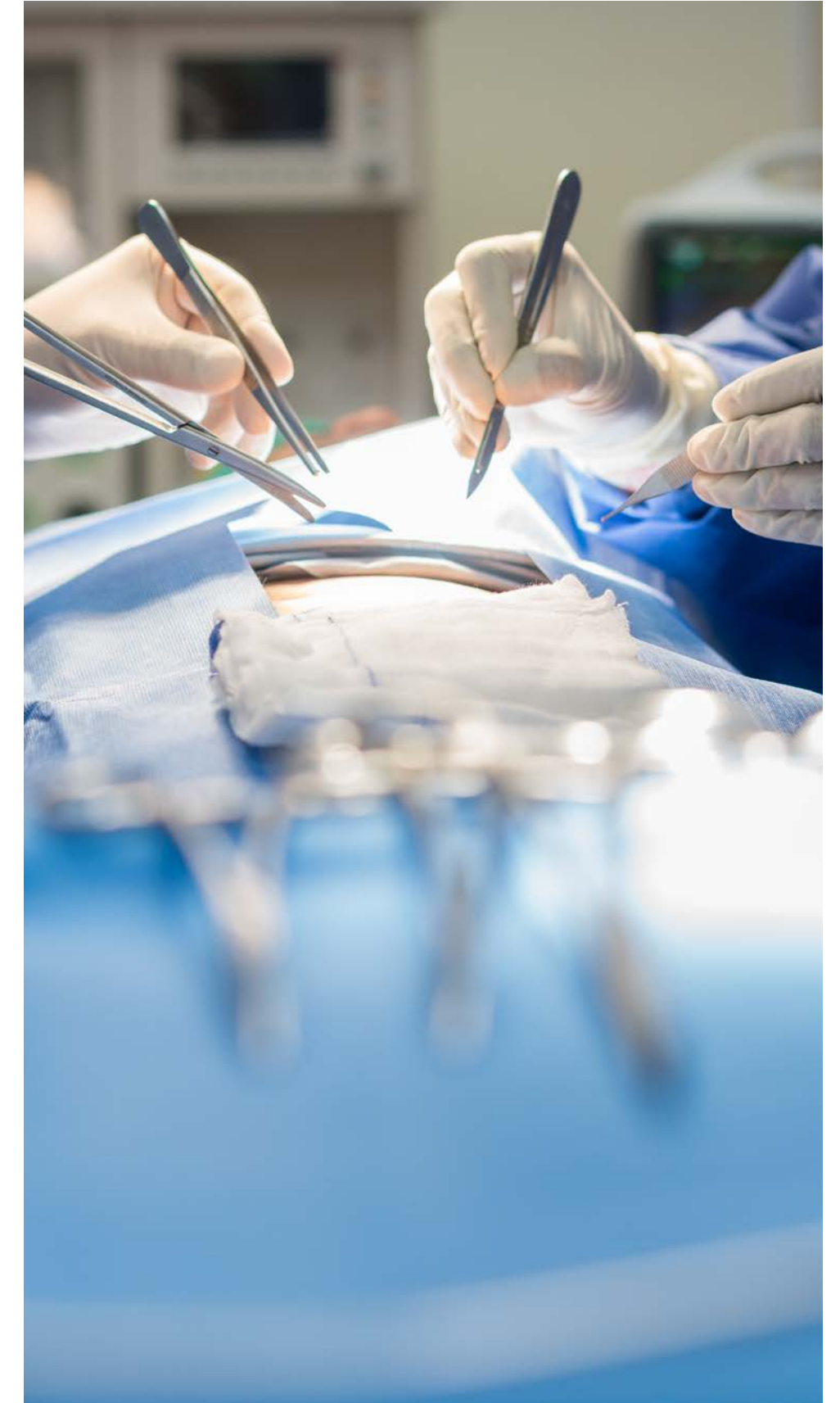
Case 2:

I do not intend to transition my legacy device to the MDR and my Directive Certificate expired prior to the publication of the Amending Regulation (EU) 2023/607

Manufacturers **holding Directives Certificates** that have been issued from 25 May 2017, and **that were still valid on 26 May 2021 and that have expired before 20 March 2023 (date of publication of Regulation (EU) 2023/607)** are allowed to continue placing on the market legacy devices until **26 May 2024** if a derogation/exemption has been granted by a Competent Authority under either Article 59(1) or Article 97(1) of the MDR before 20 March 2023. Moreover, the below conditions have to be met:

- The device must continue to comply with the applicable Directive
- No significant changes in design or intended purpose of the device are allowed
- The device does not present an unacceptable risk for patients' health and safety

Appropriate Surveillance must be guaranteed for the legacy devices.



Key elements of Amending Regulation (EU) 2023/607 – continued

Case 3

I intend to transition my legacy device to the MDR and my Directive Certificate was valid at the time of the publication of the Amending Regulation (EU) 2023/607

Manufacturers transitioning to the MDR and **holding Directives Certificates** that have been issued from 25 May 2017, **that were still valid on 26 May 2021**, that have not been withdrawn afterwards and **that were still valid at the time of publication of Regulation (EU) 2023/607** are allowed to continue placing on the market legacy devices until **26 May 2024**, if the below conditions are met:

- The device must continue to comply with the applicable Directive
- No significant changes in design or intended purpose of the device are allowed
- The device does not present an unacceptable risk for patients' health and safety

They can also benefit from the longer validity of Directive Certificates for legacy devices **(until the end of 2027/2028 based on device classification)** if the following additional conditions are met:

- No later than 26 May 2024, manufacturers have put in place an MDR compliant QMS and have lodged a formal application with a Notified Body for MDR Conformity Assessment
- No later than 26 September 2024, a formal agreement with a Notified Body has been signed in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device

Appropriate Surveillance must be guaranteed for the legacy devices.

Case 4

I intend to transition my legacy device to the MDR and my Directive Certificate expired prior to the publication of the Amending Regulation (EU) 2023/607

Manufacturers transitioning to the MDR and **holding Directives Certificates** that have been issued from 25 May 2017, **that were still valid on 26 May 2021** and **that have expired before 20 March 2023 (date of publication of Regulation (EU) 2023/607)**, are allowed to continue placing on the market legacy devices and benefit from the extended transition timelines until **26 May 2024 only if one of the following conditions is fulfilled:**

- A derogation/exemption has been granted by a Competent Authority under either Article 59(1) or Article 97(1) of the MDR before 20 March 2023

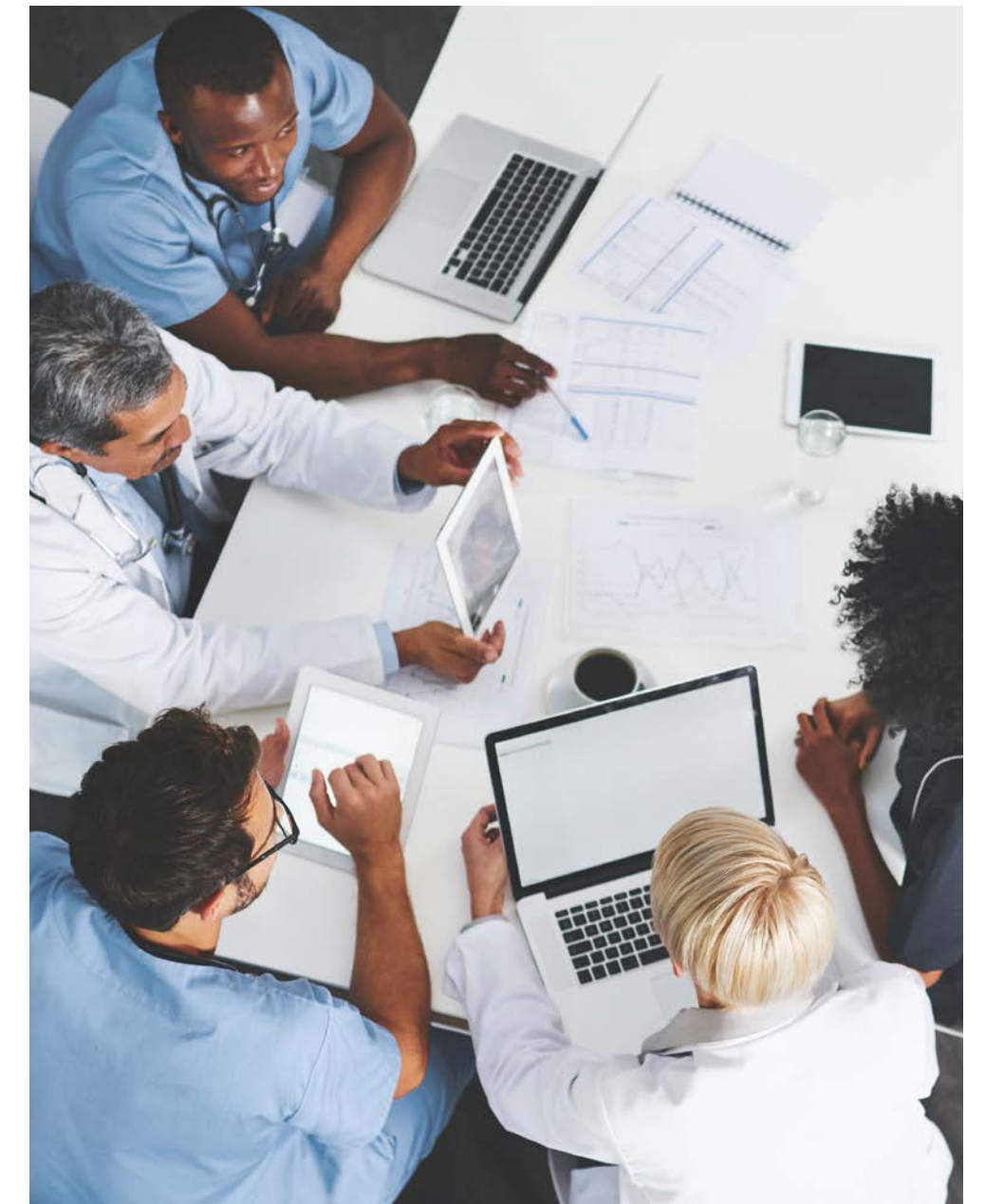
OR

- The manufacturer had applied for MDR and signed a formal written agreement with a Notified Body prior to the expiry of those Directive Certificates in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device

They can also benefit from the longer validity of Directive Certificates for legacy devices **(until the end of 2027/2028 based on device classification)** if the following conditions are met:

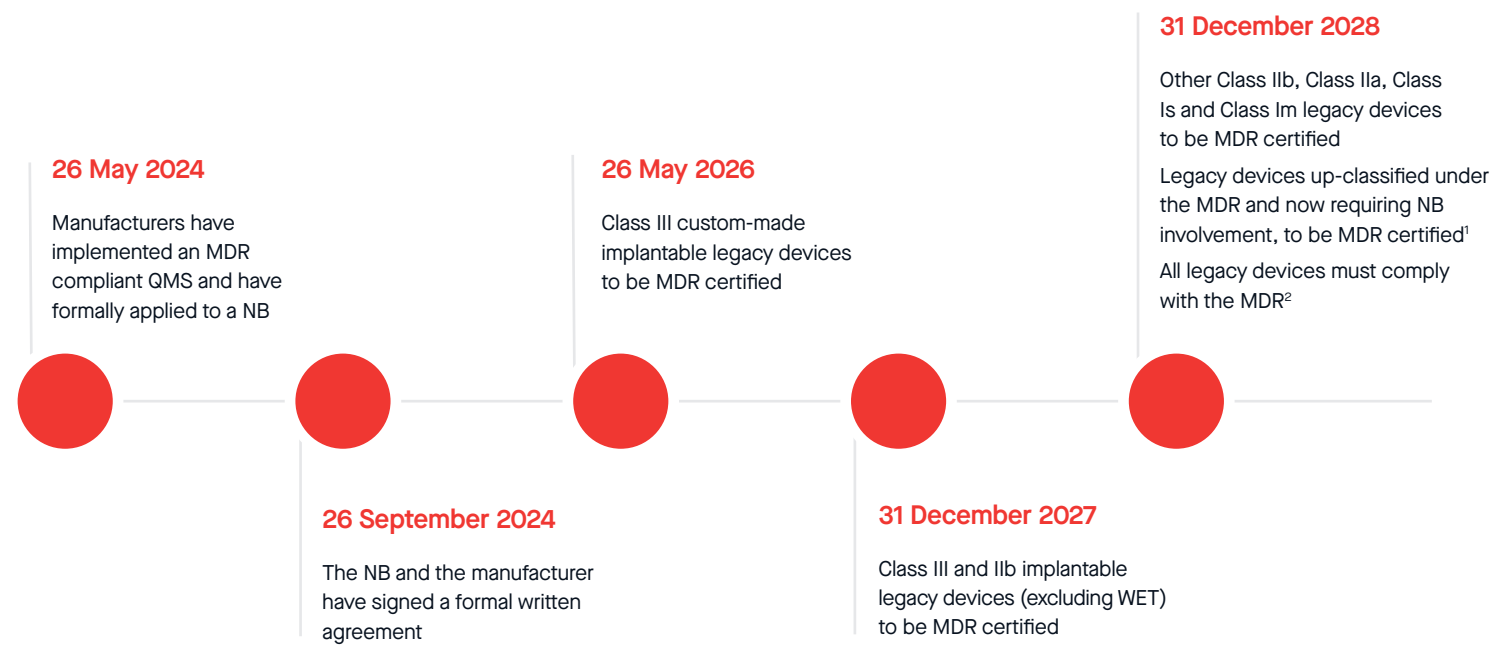
- No later than 26 May 2024, manufacturers have put in place an MDR compliant QMS and have lodged a formal application with a Notified Body for MDR Conformity Assessment
- No later than 26 September 2024, a formal agreement with a Notified Body has been signed in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device

Appropriate Surveillance must be guaranteed for legacy devices.



Note: In cases where the manufacturer lodges an MDR application with a different Notified Body to the one that issued the Directive Certificate, the Regulation allows the MDR Notified Body to take over the appropriate surveillance of the devices covered by the Directive Certificates issued by the other Notified Body, subject to an agreement between the two Notified Bodies and the manufacturer.

MDR transition timeline



¹ Only for legacy devices whose Declaration of Conformity (DoC) was signed by 26 May 2021 (e.g., Class Ir)

² The sell-off period has been removed. Legacy devices placed on the market before the end of the transition period can be made further available on the market without legal time restrictions



Why to lodge your MDR application now?

While additional time is now available for completing the MDR transition, BSI strongly recommends that manufacturers who are yet to make their MDR application, to submit it as soon as possible for the following reasons:

- For legacy devices to benefit from extended transition timelines (2026, 2027, 2028) manufacturers are required to lodge an MDR application to a Notified Body by May 2024 and sign a formal written agreement by September 2024
- Delaying your applications will mean that, when submitted, the applications will be added to the end of the review queue thus facing the risk of delayed conformity assessment
- Manufacturers are not allowed to make significant changes to the design or intended purpose of their devices under the Directives even under the longer transition timelines
- BSI may not be able to process your MDR application for a legacy device in a timely manner if it is submitted very close to the application cut-off deadline (May 2024) due to the anticipated rush of last-minute applications thus facing the risk of not benefitting from the longer transition timelines



If you have additional questions you can email us at:
medicaldevices@bsigroup.com



Read more about our certification services on our website
bsigroup.com/medical



Find us on **LinkedIn**



Dedicated webinar

Stay tuned to register for upcoming webinars on MDR transition and associated topics.



Where can I find additional information?

You can visit our **MDR dedicated** webpage to access additional resources to support you, along with a **FAQ document** with answers to most frequently asked questions in relation to this Regulation and associated topics.