Your partner
in progress

Time for your IVDR application is now

Be prepared for the
new transition timelines

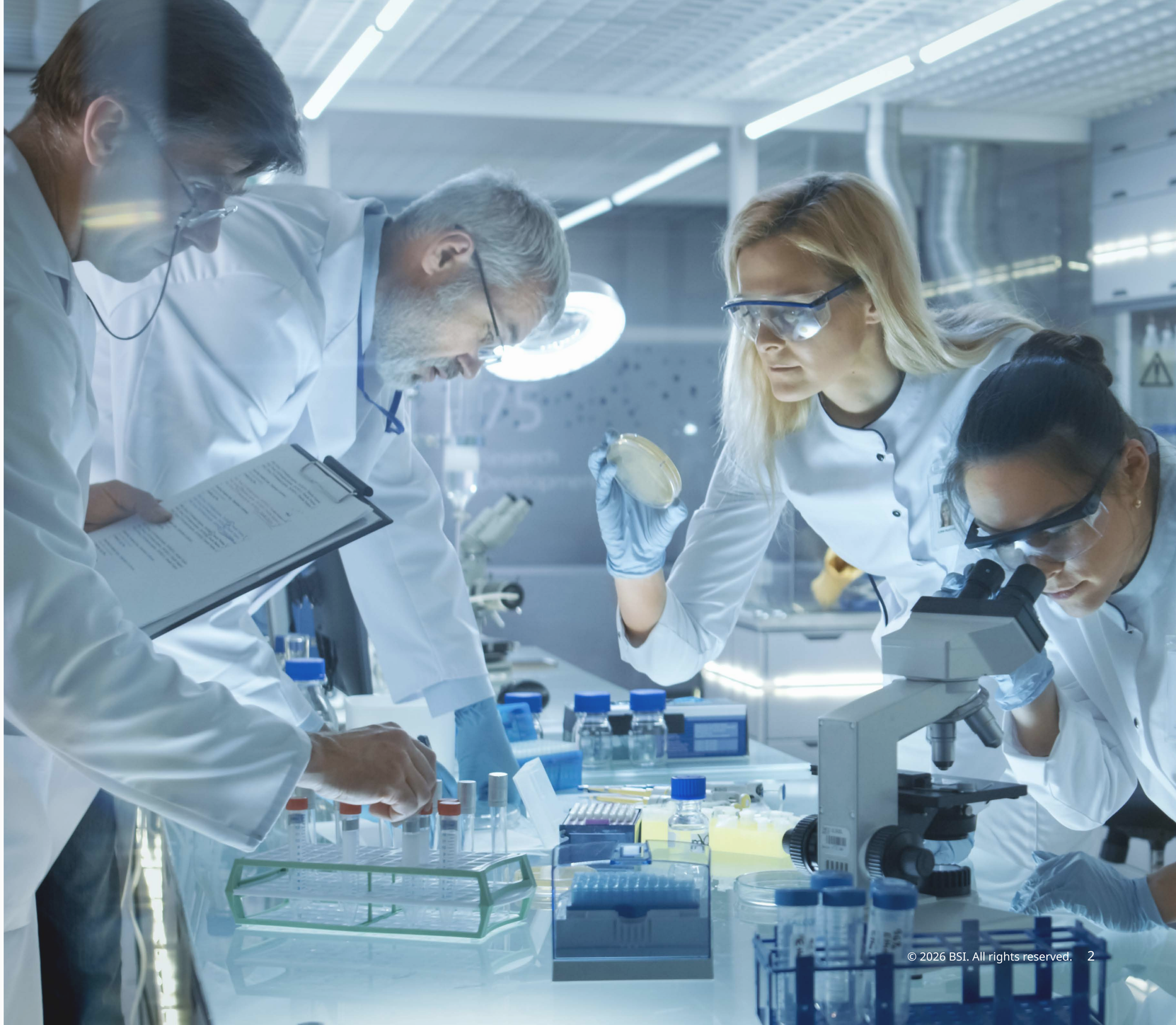
What happened?

On July 2024, the **Regulation (EU) 2024/1860** amending the 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 IVD medical devices in EU due to the slower than anticipated transition from the In Vitro Diagnostic Directive to the IVDR.

What are the implications?

The Amending Regulation extends the IVDR transition timelines while also recognizing as valid previously issued IVDD 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 Directive while they continue the transition of their devices to the IVDR.



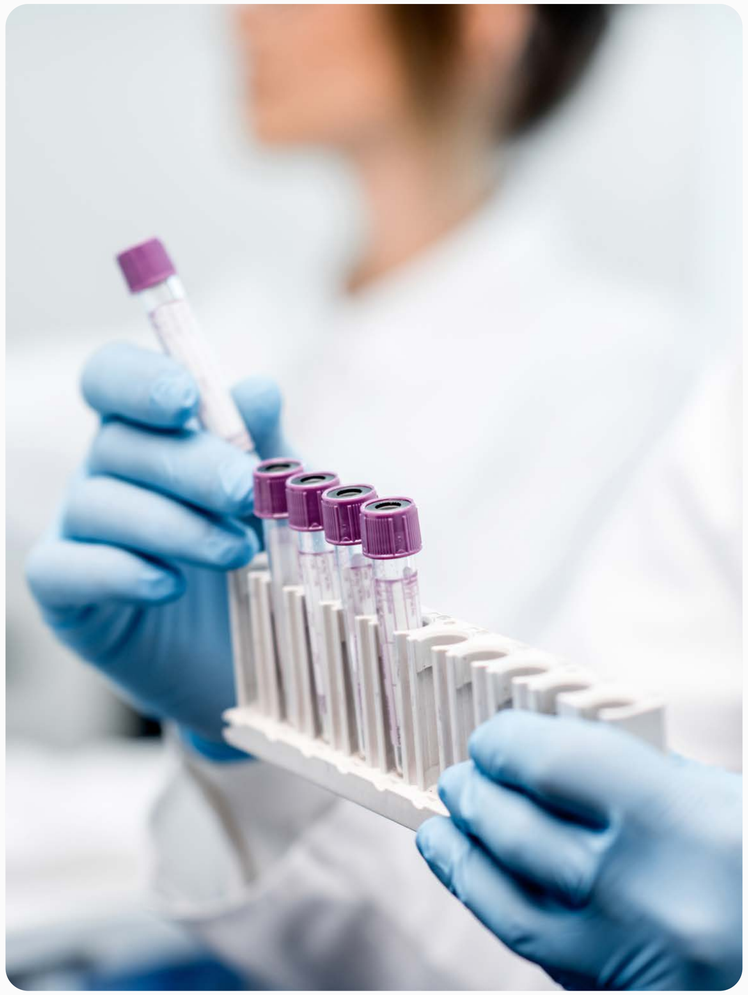
Key elements of Amending Regulation (EU) 2024/1860

Case 1

I do not intend to transition my legacy device to the IVDR and my Directive Certificate was valid at the time of the publication of the Amending Regulation (EU) 2024/1860.

Manufacturers **holding a Directive Certificate** that has been issued from 25 May 2017, **that was still valid on 26 May 2022**, that has not been withdrawn afterwards and **that was still valid at the time of publication of Regulation (EU) 2024/1860** are allowed to continue placing on the market legacy devices until **26 May 2025**, 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 IVDR and my Directive Certificate expired prior to the publication of the Amending Regulation (EU) 2024/1860.

Manufacturers **holding a Directive Certificate** that have been issued from 25 May 2017, and **that was still valid on 26 May 2022 and that have expired before publication of Regulation (EU) 2024/1860**, are allowed to continue placing on the market legacy devices until **26 May 2025** if a derogation/exemption has been granted by a Competent Authority under either Article 54(1) or Article 92(1) of the IVDR before 9 July 2024 (Amending Regulation publication date). 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) 2024/1860

Case 3

I intend to transition my legacy device to the IVDR and my Directive Certificate was valid at the time of the publication of the Amending Regulation (EU) 2024/1860.

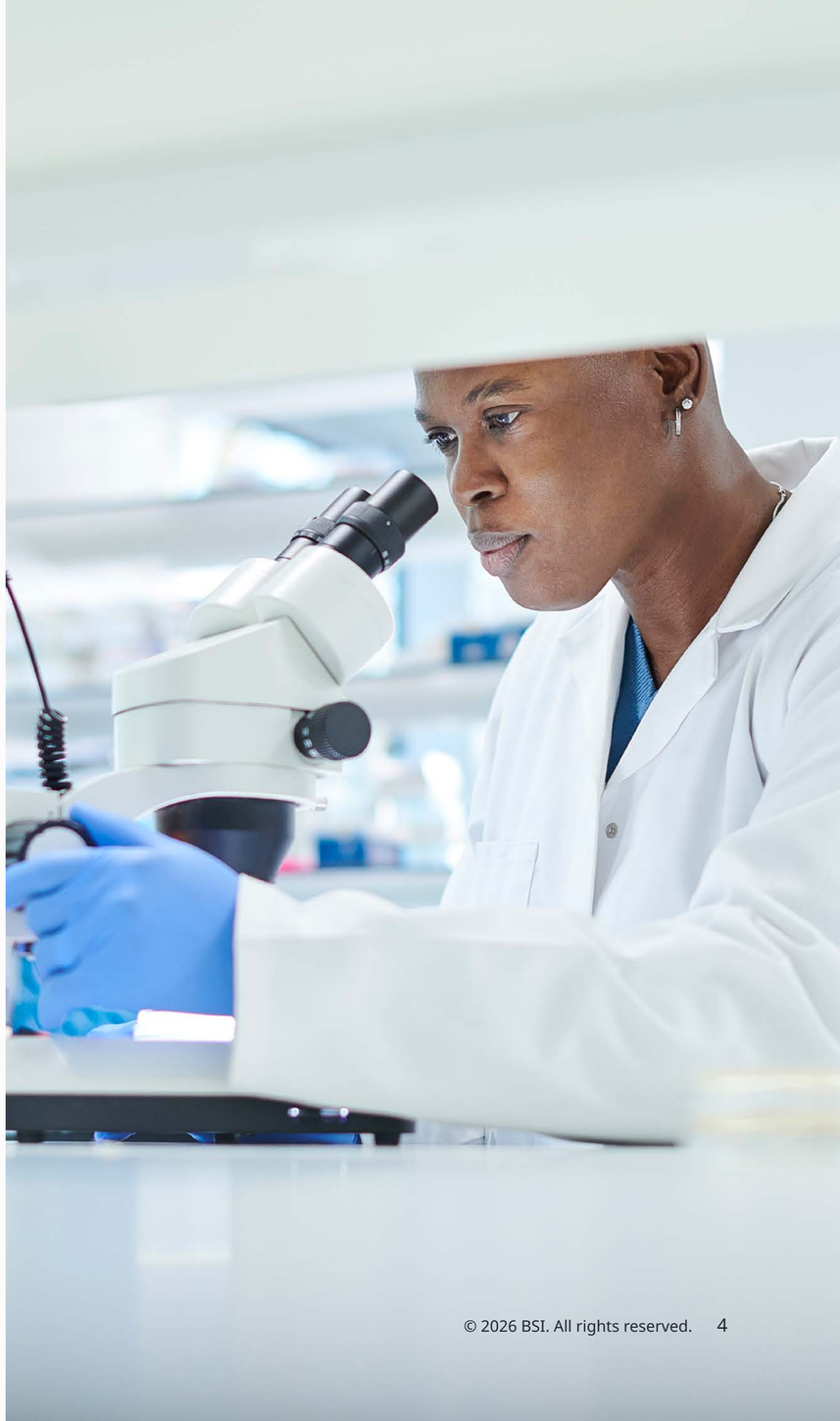
Manufacturers transitioning to the IVDR and **holding a Directive Certificate** that has been issued from 25 May 2017, **that was still valid on 26 May 2022**, that have not been withdrawn afterwards **and that were still valid at the time of publication of Regulation (EU) 2024/1860** are allowed to continue placing on the market legacy devices until **26 May 2025**, if the below conditions are met:

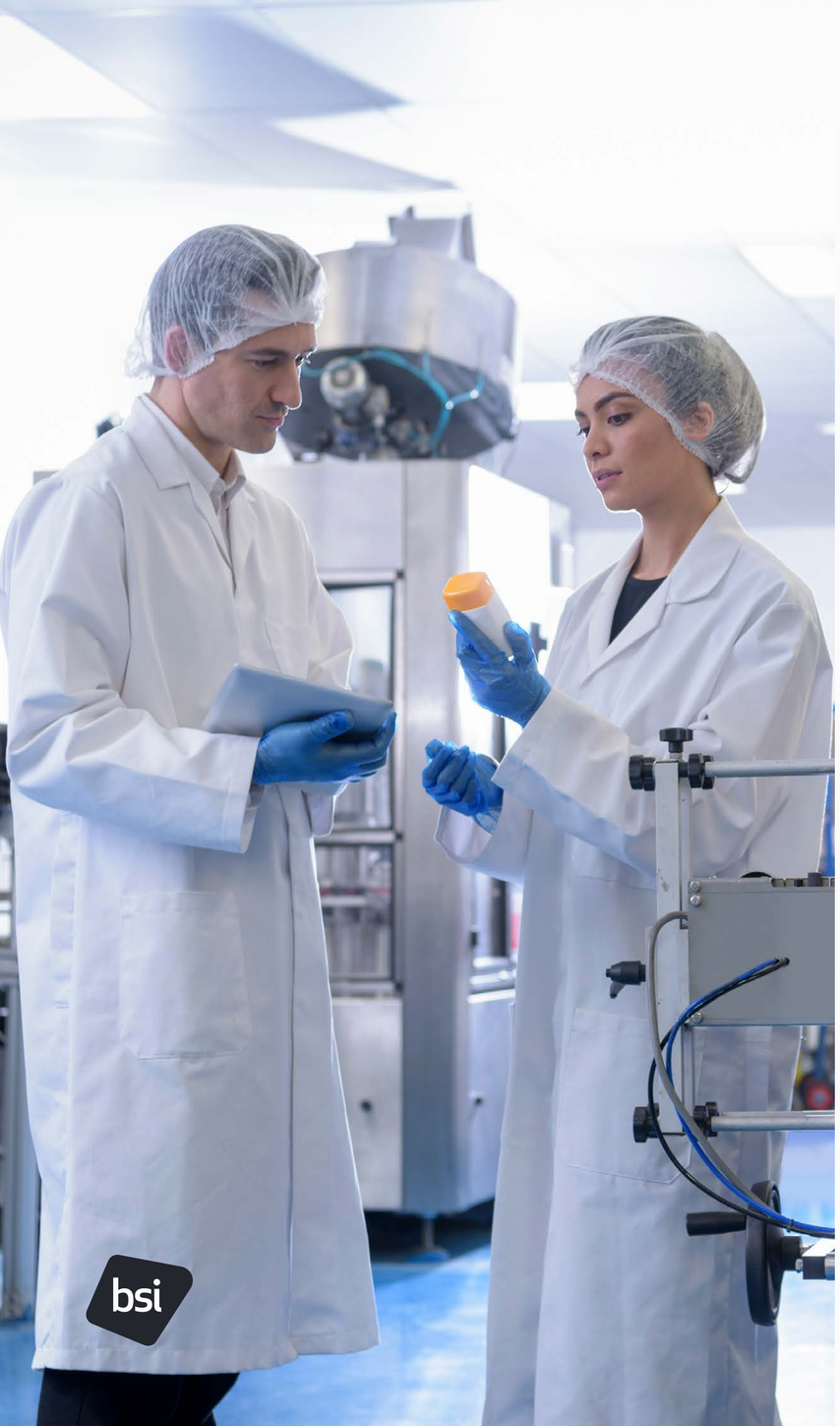
- The device must continue to comply with the applicable Directive.
- No significant changes in design or intended purpose of the device are allowed.
- The device does not present an unacceptable risk for patients' health and safety.

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

- No later than 26 May 2025, manufacturers have put in place an IVD compliant QMS and have lodged a formal application with a Notified Body for IVDR Conformity Assessment.
- No later than 26 September 2025, 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.





Key elements of Amending Regulation (EU) 2024/1860

Case 4

I intend to transition my legacy device to the IVDR and my Directive Certificate expired prior to the publication of the Amending Regulation (EU) 2024/1860.

Manufacturers transitioning to the IVDR and **holding a Directive Certificate** that have been issued from 25 May 2017, **that was still valid on 26 May 2022** and **that have expired before 9 July 2024 (date of publication of Regulation (EU) 2024/1860)**, are allowed to continue placing on the market legacy devices and benefit from the extended transition timelines until **26 May 2025 only if one of the following conditions is fulfilled**:

- A derogation/exemption has been granted by a Competent Authority under either Article 54(1) or Article 92(1) of the IVDR before 9 July 2024.

or

- The manufacturer had applied for IVDR 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 based on device classification)** if the following conditions are met:

- No later than 26 May 2025, manufacturers have put in place an IVDR compliant QMS and have lodged a formal application with a Notified Body for IVDR Conformity Assessment.
- No later than 26 September 2025, 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 IVDR application with a different Notified Body to the one that issued the Directive Certificate, the Regulation allows the IVDR Notified Body to take over the appropriate surveillance of the devices covered by the Directive Certificate issued by the other Notified Body, subject to an agreement between the two Notified Bodies and the manufacturer.

IVDR transition timeline

	IVDR compliant QMS	Formal application lodged	Formal written agreement with a Notified Body signed	Transition deadline
IVDD certified devices[1]	26 May 2025	26 May 2025	26 September 2025	31 December 2027
Class D self-declared[2]		26 May 2026	26 September 2026	31 December 2028
Class C self-declared[2]		26 May 2027	26 September 2027	31 December 2029
Class B and A[2] Sterile self-declared				

Notes

[1] **IVDD certified devices:** IVDD Certification from a Notified Body.

[2] **IVDD self-declared devices:** IVDs on the market under IVDD that did not need a Notified Body Certification.

The sell-off period for self-certified IVDs already placed on the market under the IVDD has been removed. These devices can be made further available on the market without legal time restrictions. For in-house devices, the requirement to justify that an equivalent device is not available on the market is postponed until May 2028.

Why to lodge your IVDR application now?

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

- For legacy devices to benefit from extended transition timelines (2027, 2028, 2029) manufacturers are required to lodge an IVDR application to a Notified Body by a specific date (May 2025, 2026, 2027 depending on the classification) and sign a formal written agreement within four month (September 2025, 2026, 2027 respectively).
- 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 Directive even under the longer transition timelines.
- BSI may not be able to process your IVDR application for a legacy device in a timely manner if it is submitted very close to the relevant application cut-off deadline due to the anticipated rush of last-minute applications thus facing the risk of not benefitting from the longer transition timelines.

Where can I find additional information?

You can visit our **IVDR dedicated webpage** to access additional resources to support you. Stay tuned to access upcoming guidance.

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

Get in touch

Whether you are starting the certification process, looking to transfer or need to discuss your options, we can guide you through the process.

Talk to us

Your partner in progress

Read about our certification services at:
bsigroup.com/medical

Email us with questions at:
medicaldevices@bsigroup.com

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