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Transfer of Appropriate Surveillance

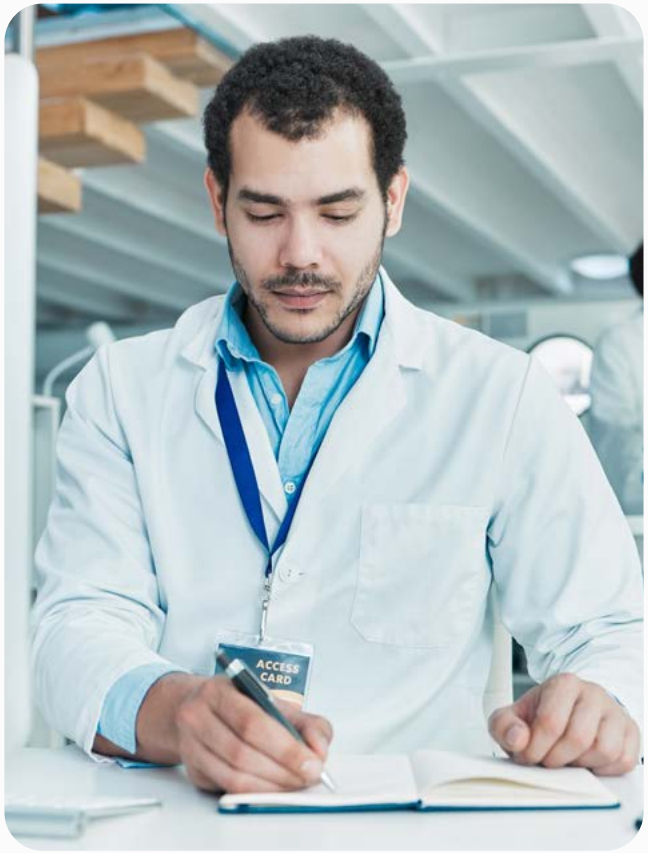
Transfer to BSI under (EU) 2024/1860

Background

On 9 July 2024, the Regulation (EU) 2024/1860 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.

The amending Regulation extends the IVDR transition timelines while also recognising as valid previously issued IVDD certificates for the duration of those longer transition timelines. This allows manufacturers, that meet other specific conditions set out in the amending Regulation, to continue placing their devices on the market based on compliance to the IVD Directive while they continue the transition of their devices to the IVDR.

Among the conditions set out in the Regulation (EU) 2024/1860, as per IVDR Article 110.3(e), the Notified Body that issued the IVD Directive



certificate shall continue to be responsible for the appropriate surveillance in respect of the applicable requirements relating to the devices it has certified, unless the manufacturer has agreed with the Notified Body it signed an IVDR written agreement with, that the IVDR Notified Body shall carry out such surveillance.

No later than 26 September 2025, the Notified Body with whom the manufacturer signed the IVDR written agreement shall be responsible for the surveillance in respect of the devices covered by the IVDR written agreement. Where the IVDR written agreement covers a device intended to substitute a device which has a certificate that was issued in accordance with IVDD, the surveillance shall be conducted in respect of the device that is being substituted.

This leaflet will guide you through the process of transfer of appropriate surveillance from another Notified Body to BSI according to (EU) 2024/1860.

Transferring* appropriate surveillance to BSI

In cases where the manufacturer has their IVDR application with a different Notified Body to the one that issued the IVD Directive Certificate, the amending Regulation allows the IVDR Notified Body to take over the appropriate surveillance of the devices covered by the IVD Directive certificate(s) issued by the other Notified Body, subject to a transfer agreement between the two Notified Bodies and the manufacturer. **Transfer of appropriate surveillance to the IVDR Notified Body (NB) must be completed by 26th September 2025.**

If you have signed a written agreement under IVDR conformity assessment with BSI while your legacy devices are covered by an IVD Directive Certificate that has been issued by another Notified Body, BSI can take over the appropriate surveillance of your legacy devices. This is subject to a tripartite transfer agreement between the manufacturer, BSI (incoming Notified Body) and the outgoing Notified Body (the Notified Body that issued the Directive certificate).

It is the manufacturers responsibility to request BSI to transfer the appropriate surveillance of those legacy devices they intend to keep placing on the market.

BSI will not initiate the transfer of appropriate surveillance unless requested by the manufacturer.

If you wish to:

- Apply under IVDR with BSI and transfer the appropriate surveillance of your legacy devices.
- Request a combined transfer of an IVDR application and appropriate surveillance of relevant legacy devices to BSI.

Contact our sales department as soon as possible: medicaldevices@bsigroup.com

Be sure to contact BSI as soon as possible, to allow sufficient time to process the transfer before the 26 September 2025 deadline.

* Self-declared legacy devices are not subject to the transfer of appropriate surveillance

The process

Click a block to reveal additional notes

Manufacturer contacts BSI to request the transfer of appropriate surveillance

BSI will provide a tripartite transfer agreement to be completed and signed by the manufacturer

BSI will provide the manufacturer an application form and quotation

Manufacturer forwards the completed and signed transfer agreement to BSI

BSI checks information on the transfer agreement, signs it and sends it back to the manufacturer

The manufacturer sends the transfer agreement to the outgoing NB

The outgoing NB checks, signs and sends the transfer agreement to the manufacturer and to the incoming NB (BSI)

Transfer activities can start

BSI will perform checks and activities, as needed, to transfer appropriate surveillance

BSI will issue a letter stating that BSI is in charge of appropriate surveillance activities for transferred devices

Standard certificate maintenance

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For more guidance visit our **IVDR dedicated webpage** where you can find additional resources to support you:

- **IVDR Transition Guidance**
- **IVDR Transition FAQs**
- **IVDR timeline**

BSI Assurance UK Ltd (0086)

Kitemark Court,
Davy Avenue, Knowlhill,
Milton Keynes MK5 8PP
United Kingdom

+44 345 080 9000

Find our services at
bsigroup.com/medical

BSI Group The Netherlands B.V. (2797)

Say Building,
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

+31 20 346 0780

Email us at
medicaldevices@bsigroup.com

BSI Group America Inc.

12950 Worldgate Drive,
Suite 800
Herndon, VA 20170
USA

+1 800 862 4977

Find us on
LinkedIn