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Contact us
+44 345 080 9000
medicaldevices@bsigroup.com

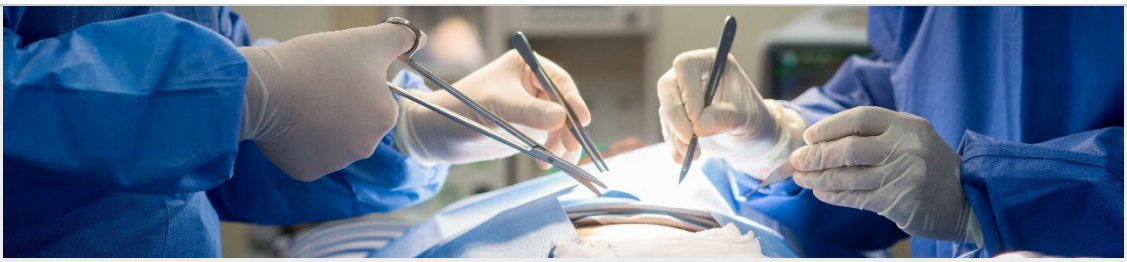
Regulatory review

Your monthly medical devices update

June 2023

Featured in this Newsletter

The time to make your MDR application is now!



According to Amending Regulation (EU) 2023/607, if you are transitioning your devices to the MDR, you will be able to benefit from extended validity of your directive certificates (until the end of 2027/2028 based on the device classification) for legacy devices if some conditions are met.

Among these, by 26 May 2024 you have to put in place an MDR compliant QMS and lodge a formal application with a Notified Body for MDR Conformity Assessment. No later than 26 September 2024, a formal agreement with the Notified Body must be signed.

We strongly recommend that you do not wait until May 2024 to make your MDR application. We encourage you to apply with BSI as soon as possible and well in advance of the above deadlines.

For more guidance visit our MDR dedicated webpage and our FAQs.

BSI Regulatory Services adopts new mission statement

As a trusted partner in the medical technology industry, we are constantly looking for ways to improve our services and meet your needs. That's why we have adopted a renewed mission statement to better align with our vision and values:

Our mission is to ensure patient safety whilst supporting timely market access to medical technology in a sustainable manner. We strive to set the global standard through conducting impartial, responsive, robust, and thorough conformity assessments, evaluations, and certifications that are recognised and trusted worldwide.

In today's dynamic healthcare landscape, where innovation is essential, but safety cannot be compromised, we recognise the critical role we play in safeguarding patient well-being. Our unwavering commitment to upholding the highest standards of quality, reliability, and compliance ensures that the medical technologies you develop and seek market access for are rigorously assessed, meeting regulatory requirements and industry benchmarks.

We understand the importance of timely market access for your products without compromising safety or sustainability. By partnering with BSI, you can therefore trust that our services are designed to streamline the regulatory process, supporting your journey to bring medical technologies to market efficiently and responsibly.

We invite you to explore the breadth of our regulatory services and experience the expertise and dedication of our team. Together, we can shape the future of medical technology, ensuring its accessibility, reliability, and, most importantly, patient safety.

Visit Webpage

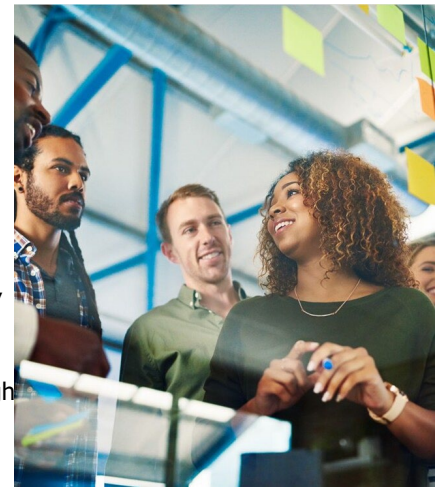
Developing and maintaining a Quality Management System for IVDs

In Vitro Diagnostic manufacturers have to comply with several requirements to place IVDs on the market. To put in place an IVDR compliant QMS is one of these.

Take a look to our whitepaper on "Developing and maintaining a Quality Management System for IVDs" and explore QMS requirements according to the IVDR.

View Whitepaper

New SMEs space now available



Globally, 85% of the manufacturers BSI works with across all regulatory certification services are SMEs.

We fully understand the difficulties you may encounter to place your medical device on the market.
To guide you in navigating the highly regulated MedTech sector, we developed an SMEs dedicated space where you can explore and learn about the certification process from application through conformity assessment and much more!

Visit our SMEs dedicated webpage and start your journey.

SMEs dedicated webpage

BSI's new scope designation for non-standard sterilization modalities for sterile medical devices

BSI The Netherlands Notified Body (2797) is now ready to support the strategic goals of the medical device industry as it seeks to introduce new technologies and drive sustainability.

On 8 March 2023, BSI's scopes of designation under MDR and IVDR were expanded to include six new sterilization modalities. We are the first Notified Body to achieve this designation to allow CE marked devices using such technologies onto the EU market.

Read the release.

NANDO designation scope

Critical Regulatory News

- UKCA standstill period extension and acceptance of Amending Regulation (EU) 2023/607 Read More>>
- Periodic Safety Update Report (PSUR) and Summary of Safety and Clinical Performance (SSCP) / Summary of Safety and Performance (SSP) Read more>>

On demand Webinars

An overview of the MDR Conformity Assessment Routes in the AIMD space

Listen back to our webinar, 'An overview of the MDR Conformity Assessment Routes in the AIMD space', presented by Thomas Doerge, Global Head of Active Implantable Medical Devices (AIMD) BSI, Simon Lidgate, Technical Team Manager, AIMD, BSI and Jazzmyne Buckels, Technical Team Manager, AIMD, BSI.

The webinar discussed challenges faced in planning for an AIMD technical documentation submission, as well as general lessons learnt about review timelines and associated service levels BSI can offer.

The webinar was of particular interest to all SMEs who intend to apply for CE marking under the Medical Device Regulation.

Watch on demand webinar

EU AI Act Explained: Navigating the new legislation with BSI

Listen back to our webinar, 'EU AI Act Explained: Navigating the new legislation with BSI', presented by Aris Tzavaras, Head of AI Notified Body, Regulatory Services, BSI, and some of the AI team from BSI.

The webinar discussed in detail the EU AI Act, looking at the framework, approach, timeline, and impact of this new legislation on AI providers and manufacturers.

Watch on demand webinar

BSI Compliance Navigator

bsi. compliance navigator

Implementing the European Union Medical Devices Regulations Latest white paper is available for download

The European Union (EU) Medical Devices Regulation (EU 2017/745) (MDR) and the In Vitro Diagnostic Medical Devices Regulation (EU 2017/746) (IVDR), now apply. Important terms used in the regulations are 'entry into force' and 'date of application'.

Read the full white paper, which has been updated by Eamonn Hoxey, Director, E V Hoxey Ltd, Cirencester, UK.

Download Now

Click here to start your free trial of Compliance Navigator today.

Events for your calendar

We have some fantastic events for 2023. Take a look now at our calendar of events for 2023.

Don’t miss the opportunity to interact with BSI experts or connect with our commercial team to discuss your certification requirements. Find out more about our latest Events and Conferences.

bsi.

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