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Regulatory review

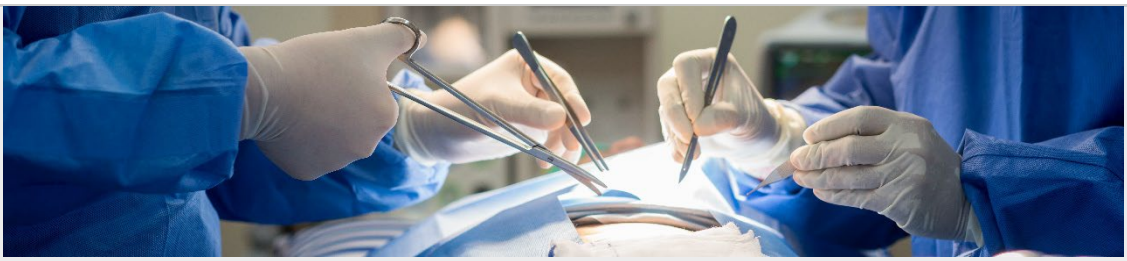
Your monthly medical devices update

Summer 2023

Featured in this Newsletter

We've combined this edition of your Regulatory review into a summer edition. Your monthly medical device update will be back in September.

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 awarded local ISO 13485 with Singapore Accreditation Council (SAC)

On 5 June 2023, BSI was awarded accreditation in the field of "Medical Devices Quality Management System "- ISO 13485:2016 with Singapore Accreditation Council (SAC). The accreditation covers the following main Technical Areas: Non-Active Medical Devices, Active Medical Devices (Non-implantable), Active Implantable Medical Devices, Sterilisation Method for Medical Devices and Parts or Services.

Visit our dedicated Webpage

Hot off the press! New Microbiology and Sterile Medical Devices brochure available

BSI Microbiology and Sterile Medical Devices Team has just released a new brochure. Discover our sterilization services, how to prepare for microbiology assessment and much more!

For additional resources, visit our dedicated Microbiology and Sterile Medical Devices webpage.

Visit Webpage

Medical Devices training portfolio available

BSI Training Academy offers a comprehensive training portfolio delivered by industry experts from all around the world! Our highly specialized courses provide an in-depth understanding on key topics regulating medical devices, IVDs and Quality Management System, increasing your knowledge on compliance, implementation, and maintenance of regulatory requirements.

Visit our dedicated webpage and enrol today!

Visit Webpage

BSI celebrates issuing its 1000th MDR Certificate

We are delighted to announce that, on 26 June 2023, BSI issued its 1000th Medical Devices Regulation (MDR) certificate.

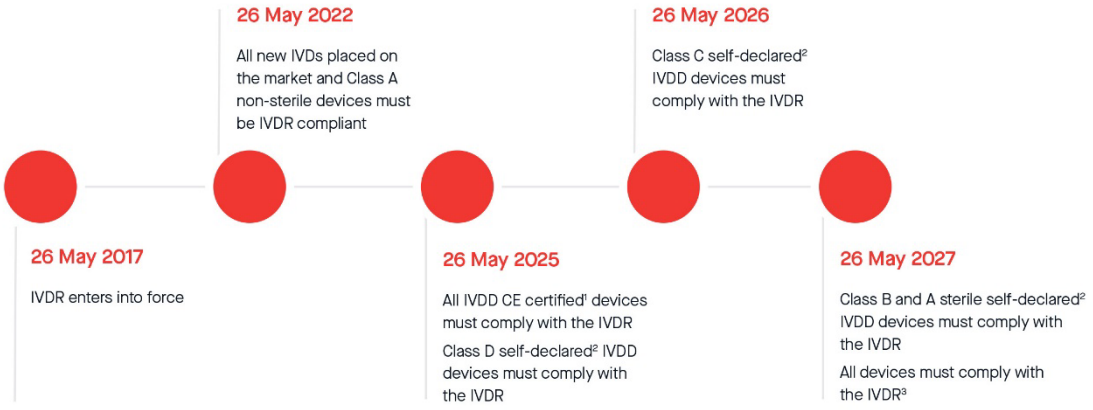
This hugely significant milestone highlights BSI's mission to ensure timely market access to safe medical devices for European patients and beyond, while upholding the highest standards of regulatory compliance. It also accounts for over 30% of all certificates issued by the 38 notified bodies operating in this field.

Dr. Suzanne Halliday, Vice President of Regulatory, emphasised the considerable effort required for the conformity assessments under the MDR:

She said *"I commend my colleagues for reaching this remarkable milestone and am proud of their dedication and hard work. Our staff had to learn about and assess against a new regulation in the background of a continuously evolving regulatory landscape with new guidance being published at a rapid pace"*.

We'd like to thank each of our clients for placing your trust in us, and for helping us to achieve this exceptional industry feat. We look forward to continuing to work with you all.

Time for your IVDR application is now



1 IVDD Certification from a Notified Body
2 IVDs on the market under IVDD that did not need a Notified Body Certification
3 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.

The date of IVDR application has not changed (26 May 2022) - It is the responsibility of the manufacturer to understand the deadlines and complete the conformity assessment process in time to ensure their products remain on the market.

- All new IVDs and Class A non-sterile devices already need to demonstrate compliance with the IVDR as of date of application (26 May 2022)
- For legacy devices, the new IVDR Amending Regulation - published on 26 January 2022 - extends the transition deadlines according to the new risk class of the device, with caveats (e.g., no significant changes)
- For legacy devices that were placed on the market through a valid IVDD Certificate (Annex II List A, Annex II List B and self-tests), the Certificate will lose expiry as of 26 May 2025
- On 27 May 2027, all IVD devices must comply with IVDR

You can email us at medicaldevices@bsigroup.com or directly request a quote.

Driving action and creating change against antimicrobial resistance

According to the World Health Organization, antimicrobial resistance (AMR) has been declared a top 10 global public health threat and is expected to get worse unless action is taken. AMR threatens to undermine the basis of modern medicine by rendering the antibiotics used to treat and prevent infections ineffective. Resistance can come from many sources – BSI is working with the pharmaceutical industry to focus on the evolution of responsible manufacturing of antibiotics.

Manufacturing waste from the production of antibiotics may contribute to the development of AMR in the environment unless emissions from waste streams are effectively controlled.
BSI, in collaboration with the AMR Industry Alliance, launched an industry antibiotic manufacturing certification scheme June 2023.

To know more, take a look to our dedicated on demand webinar: here. You will learn how BSI will serve as an Assessment Body role that will enable antibiotic manufacturers to demonstrate that the environmental management, including waste water management and control requirements of the antibiotic manufacturing standard (which launched June 2022) have been satisfied.

For more information on AMR, visit our webpage.

Visit Webpage

BSI Compliance Navigator

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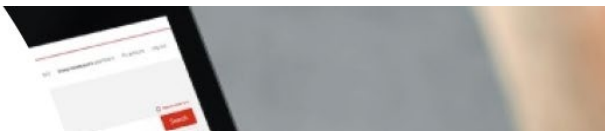

The digital revolution in regulatory document management

Compliance Navigator is the smart, simple way to work with medical and IVD device standards and regulations. Designed by regulatory experts, our online workflow tool helps teams discover, organise, and mitigate potential risks in their compliance process.

Key features:

- **Save time** - Access and search over 6500 relevant documents and standards and add the most relevant ones for your product to your own bespoke dashboard
- **Reduce risk** - Get advance warning of upcoming changes to medical device BS standards and BS-adopted medical device standards that affect your compliance
- **Coordination** - Unlimited number of users with simultaneous access
- **Expert Commentary** - Interpret standards and regulatory information via independent expert commentary and smart support guides

Start a free trial 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.

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