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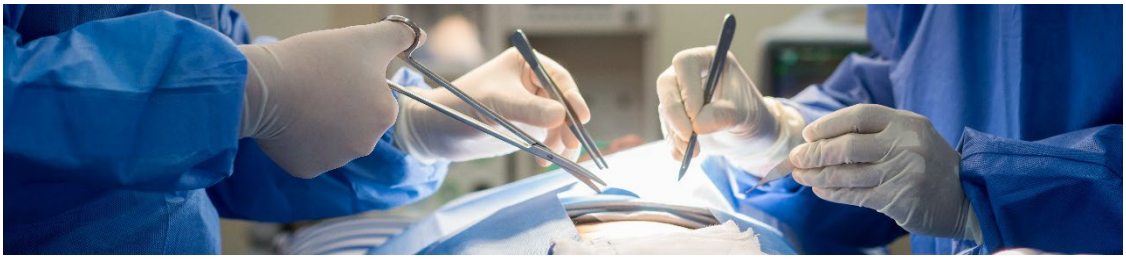
Regulatory review

Your monthly medical devices update

September 2023

Featured in this Newsletter

Time to make your MDR application is now!



On 20 March 2023, the Regulation (EU) 2023/607 amending the MDR was published in the Official Journal of the European Union (OJEU) with immediate effect.

We created an MDR transition informative leaflet for you to easily navigate the possible implications for your business and the conditions you are required to meet to continue placing medical devices on the EU market.

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.

To know more, visit our MDR dedicated webpage.

MDR dedicated webpage

The Clinical Masterclass Toolkit is back!

Following the success of our 2022 Clinical Masterclass Series of webinars, we are delighted to have delivered another successful Masterclass Series of webinars for 2023. We would like to share this detailed clinical regulatory toolkit with you, including all on-demand webinars from both 2022 and 2023, as well as whitepapers, guidance documents, FAQ's and the Best Practice Guidance document.
To access the toolkit, click on the button below.

Clinical masterclass toolkit

IVDR Technical Documentation Submission - Best Practice Guidelines

IVDR Technical Documentation Submission guidance now available!

Visit our IVDR dedicated webpage or download here the Guidelines to better understand the technical documentation submission requirements and assessment processes. Avoid delays in certification due to incomplete or poorly structured documentation submitted during the review phase.

Learn more

Webinar - EU MDR Rule 21 - Key considerations in the Conformity Assessment process

Tuesday, 3 October 2023

Join us for this insightful webinar, presented by Theresa Jeary, Principal Technical Specialist, Medicinal & Biologics Team, BSI, as she explores in-depth on Rule 21, its intent and focus on the borderline nature with medicinal products. She will also explore the key aspects that manufacturers need to consider when developing an effective regulatory strategy to successfully navigate conformity assessments and ensure Annex I to Directive 2001/83/EC requirements are met.

Register for one of the two time slots on **Tuesday 3 October 2023**

Register for AM Webinar:

9:00 - 10:00 BST - Register

Register for PM Webinar:

16:00 - 17:00 BST - Register

Blog series - Medical electrical equipment and systems EN 60601

Did you know that BSI can also provide you with testing services around EN 60601 series of standards? BSI Assurance provides medical electrical device testing services for assessing compliance with EN 60601 requirements. EN 60601 is also an harmonized standard.

Talk to BSI today and start your journey. To know more, visit our dedicated blog.

Find out more

BSI Regulatory Services Team Joins #WorldCleanUpDay 2023

We at BSI are committed to making a positive impact on the world, and our mission is to ensure patient safety whilst supporting timely market access to medical technology in a sustainable manner. With this in mind, on the 16 September, in alignment with our sustainability goals, the BSI Regulatory Services Team proudly participated in #WorldCleanUpDay 2023.

World Clean Up Day is a global initiative that encourages individuals and organizations to come together to combat litter and pollution in their communities. It was with great enthusiasm that our team took to the streets, armed with litter pickers and bags, to 'do their bit' and contribute to a cleaner, greener world.

This collective effort embodies our ongoing commitment to environmental responsibility and sustainability. At BSI, we understand the importance of protecting our planet for future generations. We invite you to learn more about our sustainability initiatives by visiting our dedicated webpage here. Thank you for joining us in making the world a cleaner and better place. Together, we can achieve remarkable results.

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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Inspiring trust for a more resilient world.