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# Regulatory review

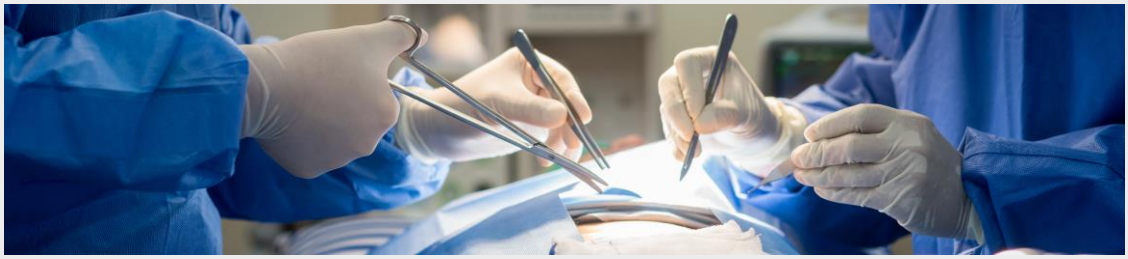
**Your monthly medical devices update**

**December 2023**

## Featured in this Newsletter



## Time for 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.

## Dr Manuela Gazzard's, Group Director, end of year message


Watch this end of year video delivered by Manuela Gazzard, Group Director, as she reflects on some of our key achievements of 2023.

As part of her end of year message, Manuela would also like to thank; 'our clients, industry partners, stakeholders, and colleagues for your continued support and commitment. I am already looking forward to 2024 and the exciting road ahead'.

Watch now

## New General Medical Devices brochure available


Take a look at the dedicated webpage to discover the full range of medical devices our General Team covers from non-active, soft tissue implanted devices and ophthalmic devices to contraceptives, wound and skin care and much more.

Visit our General Medical Devices webpage

## UKCA FAQs for Medical Devices and IVDs


Check out our UKCA FAQs brochure updated according to SI 2023 No. 627.

Now available for you to explore how to gain market access in the United Kingdom with UKCA marking.

To know more, take a look to our UKCA dedicated webpage:

Visit our UKCA webpage

## On-demand webinar - IVDR Regulatory Updates

Listen back to subject matter expert, Alex Laan, Head of IVD Notified Body as he gave a short recap on where the IVDR is (latest MDCG guidance and developments in Brussels), as well as a description of the challenges for Class D IVD's and the status on EU Reference Labs.

Watch on demand webinar


## On demand webinar - Shaping Trust in AI: Understanding 42001 Standard

On the 5 December we hosted our last webinar of the year; 'Shaping Trust in AI: Understanding 42001 Standard'. The webinar discussed the standards impact on organisations and how it can contribute to a better approach to AI readiness and commitment to ethical AI practices.

Many thanks to our subject matter experts, David Mudd, Global Head of Digital Trust Assurance, Tim McGarr, AI Market Development Lead, Alex Tazza, AI Technical Specialist Team Manager and Daniela Seneca, Regulatory Lead Artificial Intelligence, who shared their knowledge on the AI Management Systems (42001) Standard and AI readiness.

Watch on demand webinar

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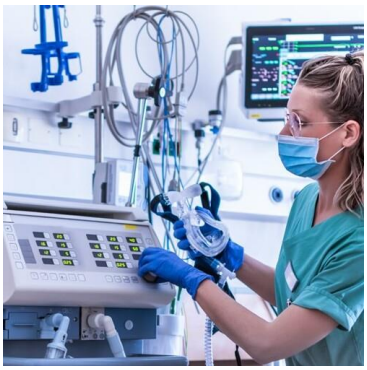
## Blog series EN 60601 - Medical electrical equipment and systems



Electrical safety testing under EN 60601 is a legal requirement which may be challenging to meet when no testing facility is locally available. Long-distance transportation across Europe exposes equipment to the risk of damage and increases costs. BSI understands the challenges

manufacturers may encounter and provides them with global reach through local expertise.

BSI offers several local testing facilities that allow manufacturers to save time and resources otherwise needed for overseas or long- distance shipments. To know more, visit our dedicated blog.

Find out more

## BSI Compliance Navigator

**BSI has a unique opportunity to help medical device manufacturers in interpreting and implementing artificial intelligence guidance into their current processes.**

Compliance Navigator, contains published artificial intelligence standards ready for medical device manufacturers to start using, including, but not limited to, BS EN ISO/IEC 22989:2023 and BS/AAMI 34971:2023. With an increasing number of AI guidance documents and standards being incorporated every month, Compliance Navigator access ensures your business stays up to date with the latest industry requirements, and enables you to assess the impact on your current product suite before it is too late.

Make sure you're prepared. Access artificial intelligence standards and guidance today, with free 30 day access to Compliance Navigator now available.

Request free access

## Events for your calendar

We have some fantastic events for 2024. Take a look now at our calendar of events for 2024.

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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