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March Newsletter

The time for your MDR application is now!

Welcome to our March Medical Devices Newsletter.

This edition, we focus on reminding you of the approaching 26 May MDR deadline for legacy devices and of the upcoming IVDR amending regulation extending transitional timelines for IVDs, along with latest updates from our Compliance Navigator. Stay tuned for upcoming webinars and events.

Talk to our experts

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 specific conditions are met.

Among these, by 26 May 2024 you must to put into place an MDR compliant QMS and lodge a formal application with a Notified Body for a 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**.
Webinar - Amending Regulation (EU) 2023/607 and possible pitfalls

Apply now

Don’t delay your IVDR compliance plans

On 23 January 2024, the EU Commission released a proposal to extend the transitional period for IVDs, when specified conditions are met. This proposal aims to mitigate the risk of shortages of IVDs by giving manufacturers and notified bodies more time, under certain conditions, to complete the necessary conformity assessment procedures, without lowering the requirements.

With only a limited number of designated Notified Bodies under the IVDR and a long lead time for conformity assessments across the industry, certification bottlenecks are still possible even if the deadlines are extended. If you do not have an agreement with a Notified Body reach out today and if your technical documentation is ready, don’t delay your IVDR application.

For more details about the proposal, read our **Press Release**.
Webinar - IVDR transition timelines extension

Talk to us today

Compliance Navigator

Machine Learning for Medical Devices (MLMD) has created a level of excitement not seen since the discovery of stem cells over 60 years ago. There are similarities between the excitement generated by the discovery of stem cells and Artificial Intelligence / Machine Learning and its use in medical devices. Click below to download the latest BSI whitepaper - AI Machine Learning and Medical Devices.

Download now

Events for your calendar

Webinar - Amending Regulation (EU) 2023/607 and possible pitfalls

Tuesday, 26 March 2024

Join this webinar to hear from subject matter expert, Maddalena Pinsi, Senior Regulatory Lead & Associate Head of Medical Devices Notified Body, as she explores the potential impact on legacy devices of non-compliance with (EU) 2023/607 conditions and MDR certification refusals.

AM webinar: 9.00 - 10.00 BST
PM webinar: 16.00 - 17.00 BST

Register here

Webinar - IVDR transition timelines extension

Tuesday, 23 April 2024

Join Alex Laan Head of IVD Notified Body at BSI in this “steps towards IVDR transition” video series, as he walks you through our 23 April webinar on IVDR transition timelines extension. Stay tuned for the upcoming episodes!

Register to webinar

Come join us at RAPS Euro Convergence 2024, taking place in Berlin on May 6-8.

6 - 8 May 2024, Berlin, Germany

Mark your calendars now for the most comprehensive regulatory affairs conference in Europe where we'll be showcasing the latest developments and expertise in the medical devices sector. Don't miss out on this chance to engage with our technical experts and commercial teams on-site.

Details here

On demand webinar - Shaping Trust in AI: A global perspective on the impact of the EU AI Act

On demand webinar

Listen back to our first in a series of webinars on the EU AI Act. This webinar covered the significant elements of the recent December deal, its potential impact on various industries, and why the Act is relevant for companies around the world.

Watch on demand

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