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April Newsletter

# Discover our Excellence Pathways

Welcome to our April Medical Devices Newsletter.

In this edition, we are pleased to introduce our Excellence Pathways, that provides experienced and efficient routes to global markets. We'd also like to remind you of the approaching 26 May MDR deadline for legacy devices and of the upcoming IVDR amending regulation extending transitional timelines for IVDs. Don't delay your compliance plans! Also in this edition, you can read all about our latest updates from our Compliance Navigator and find out about our upcoming webinars and events.

Visit our dedicated webpage

BSI provides experienced and efficient routes to global markets. Our CE and UKCA Excellence Programs are designed to support manufacturers seeking timely and effective market access. We also offer seamless Transfer services for CE, UKCA and ISO 13485 providing comprehensive support to ensure minimal level of disruption. Our services combine efficiency with the integrity, independence, and the thoroughness you expect from BSI.

Read the brochure

## The 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. 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 deadline.

To know more visit our **MDR dedicated webpage**.

Apply now

## Don’t delay your IVDR compliance plans

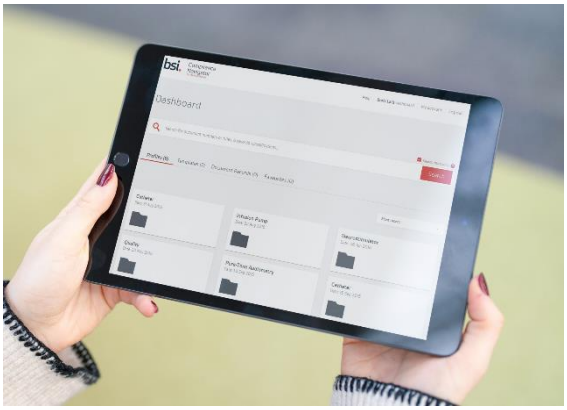
On 23 January 2024, the EU Commission released a proposal to extend the transitional period for IVDs, when specified conditions are met. This proposal aims to mitigate the risk of shortages of IVDs by giving manufacturers and notified bodies more time, under certain conditions, to complete the necessary 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

delay your IVDR application.

Talk to us today

## Compliance Navigator




Appointed by the UK Government in 1901 as the world's first National Standards Body, BSI represents UK interests at the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC) and the European Standards Organizations (CEN, CENELEC and ETSI).

Our fully digital document management system, Compliance Navigator, with over 7000 documents available, was designed by BSI and regulatory experts to help medical device manufacturers access pertinent medical device and IVD device regulations, standards and supporting guidance quickly, and organise them efficiently for reference and in preparation for regulatory audits.

Learn more

## Events for your calendar

## 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

## Webinar - Shaping Trust in AI: Ensuring Conformity of AI - enabled Medical Devices amid Regulatory Changes

Tuesday 14 May 2024 09.00 and 16.00 BST

Hear our subject matter experts Aris Tzavaras, Head of AI Notified Body, Inma Perez Ruiz, Regulatory Lead - AI Notified Body, Alex Laan, Head of IVD Notified Body and Suzanne Halliday, VP Regulatory as they discuss how the EU AI Act will interplay with the MDR and provide insights where tensions and inconsistencies are likely to emerge.

Register now

## Webinar - Maintaining Compliance: IVDR - Post certification activities

Tuesday 21 May 2024 09.00 and 16.00 BST

Hear subject matter experts James Kerr, IVD Technical Specialist & Scheme Manager and Dr Elizabeth Harrison, Global Head – IVD Medical Devices as they provide a brief overview of IVDR post-certification activities before providing an in depth look at what to expect from IVDR Technical Documentation surveillance reviews as well as explaining the requirements for PMPF, how manufacturer's might establish PMPF that adds value and what Notified Body expectations of PMPF might be.

Register now

## On demand webinar - Navigating your IVDR certification process for CE marking: How to work with your Notified Body for a sleek process

On demand webinar

Listen back to our webinar Navigating your IVDR certification process for CE marking: How to work with your Notified Body for a sleek process. The webinar discussed key steps in BSI's Certification/Review Process for CE marking under the IVDR.

Listen on demand

## On demand webinar - Amending Regulation (EU) 2023/607 and possible pitfalls

On demand webinar

Listen back to our webinar Amending Regulation (EU) 2023/607 and possible pitfalls. The

webinar discussed the potential impact on legacy devices of non-compliance with (EU) 2023/607 conditions and MDR certification refusals.

Listen on demand

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