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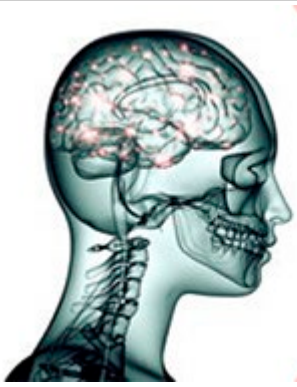


Regulatory review

Your monthly medical device update

April 2023

Featured in this Newsletter

Extended Webinar - Pathways to IVDR Compliance

25 April 2023

Pathways to IVDR compliance – 25 April 2023

Join this insightful extended webinar to hear subject matter experts, Alex Laan, BSI's Head of IVD Notified Body and Liz Harrison, Global Head of IVD, talk about the key IVDR changes and lessons learnt so far, as well as tips on preparing a comprehensive Technical Documentation and the Performance Evaluation requirements under the IVDR. You will also gain a better understanding of the status related to high-risk CDx & Class D devices.

The webinar will include:

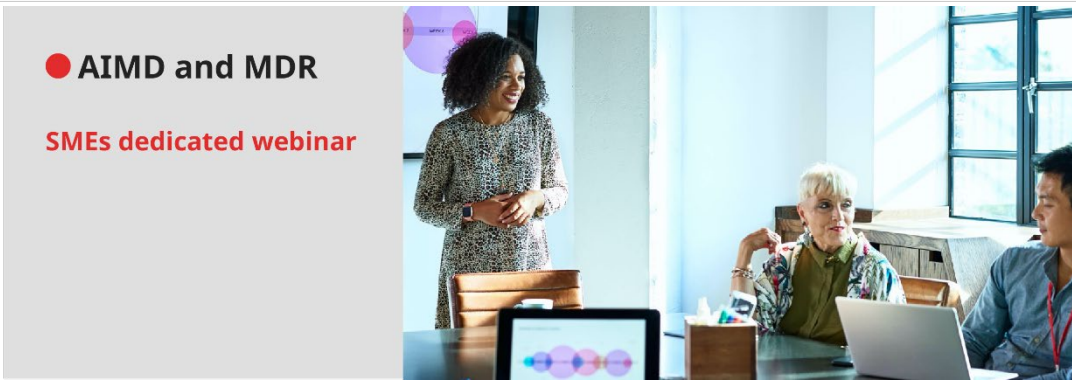
- History Lesson: Key IVDR changes… why and when?
- Telling a Story: Creating effective technical documentation
- Clinical Evidence: Understanding the requirements
- High Risk update: Current status of CDx & Class D devices
- Q&A sessions with panel

Register for this extended webinar:

25 April 2023 | 14.30 – 17.00 BST

Register here

Webinar - A SMEs tailored overview of the MDR Conformity Assessment Routes in the AIMD space



Join Thomas Doerge, Global Head of AIMD, on 24 May 2023, for the webinar; 'A SMEs tailored overview of the MDR Conformity Assessment Routes in the AIMD space'.
The webinar will focus on an overview of the MDR Conformity Assessment Routes, the application process and the review approach of BSI, tailored to SMEs in the AIMD space.
All SMEs who intend to apply for CE marking under the Medical Device Regulation should attend. Also manufacturers interested in gaining a better understanding of MDR Conformity Assessment Routes are also welcomed to join.

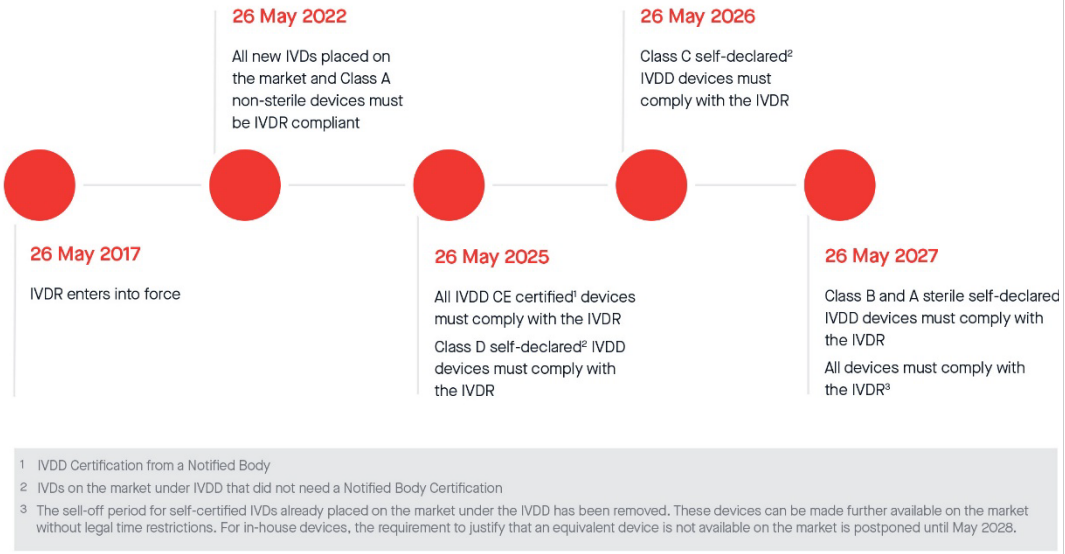
To register choose one of the time slots below on **Wednesday 24 May 2023**:

Register for AM Webinar:
9.00 – 10.00 BST Register

Register for PM Webinar:
16.00 – 17.00 BST Register

IVDR - Removal of the sell-off provisions

With the publication of the amending regulation (EU) 2023/607 in March 2023, the sell-off provisions specified in IVDR Article 110(4) have been abolished to prevent unnecessary disposal of safe in vitro diagnostic medical devices that are still in the supply chain.
Take a look at the most important timelines, including the previous amendment (EU) 2022/112.



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.

Click here to visit our dedicated webpage.

On demand Webinar – Understanding Periodic Safety Update Reports and how to submit your PSUR

Watch on demand, our recent webinar on 'Understanding Periodic Safety Update Reports and how to submit your PSUR'.

Presented by Richard Holborow, Head of Clinical Compliance and Maddalena Pinsi, Regulatory Lead, this webinar provided manufacturers with an understanding of BSI's expectation in relation to PSURs and provided an overview of the recent guidance related to PSURs (MDCG 2022-21).

Manufacturers learnt how and when to submit PSURs to BSI using the document portal and when they are required to also update and provide SSCPs alongside the PSUR.

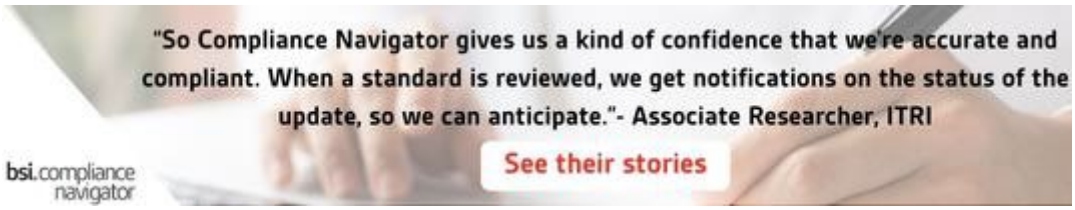
View the Recording

On demand Webinar - Extension to the MDR Transition Timelines - Impact on Manufacturers and Notified Bodies

Watch on demand, our recent webinar on the 'Extension to the MDR Transition Timelines – Impact on Manufacturers and Notified Bodies'.

Presented by Jay Katta, Regulatory Director & Head of Medical Devices Notified Body and Suzanne Halliday, VP Regulatory, this webinar focussed on this new regulation and how you, as a manufacturer, can benefit from it. The webinar also focused on conditions under which devices covered by expired MDD/AIMDD certificates can benefit from the longer transition timelines and Notified Body implementation of the new amending Regulation and potential timelines.

View the Recording



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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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