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## Regulatory review

Your monthly medical device update

April 2023

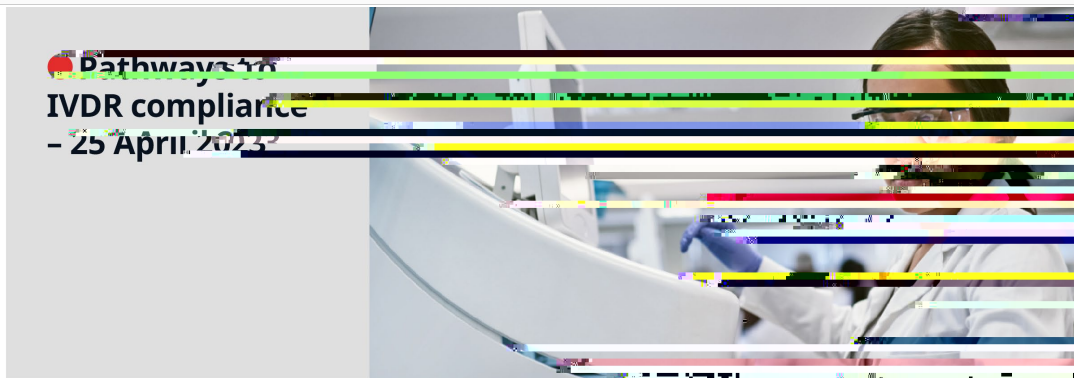
### Featured in this Newsletter

- Extended Webinar - Pathways to IVDR Compliance
- Webinar - A SMEs tailored overview of the MDR Conformity Assessment Routes in the AIMD space
- On demand Webinar - Extension to the MDR Transition Timelines - Impact on Manufacturers and Notified Bodies
- Compliance Navigator - Their words, not ours
- Events for your calendar

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### Extended Webinar - 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



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

Wednesday 24 May 2023

9.00 – 10.00 BST \_\_\_\_\_

16.00 – 17.00 BST \_\_\_\_\_

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## **IVDR - Removal of the sell-off provisions**

With the publication of the amending regulation (EU) 2023/607 in March 2023, the sell-off

[Click here](#) to visit our dedicated webpage.

**On demand Webinar -**

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**Events for your calendar**

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