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## Regulatory review

Your monthly medical device update

May 2023

### Featured in this Newsletter

- [BSI Medical Devices presents: Guide to Conformity](#)
  - [MHRA announces additional extension for UKCA standstill period](#)
  - [BSI issues its first certificate for an IVD Companion Diagnostic \(CDx\) device under the IVDR](#)
  - [New In Vitro Diagnostic brochure available](#)
  - [Ethical and Trustworthy Artificial Intelligence](#)
  - [On demand webinar - Pathways to IVDR Compliance](#)
  - [Open doors for NBOp \(Notified Body Opinion\) under MDR Article 117](#)
  - [Latest white paper is available for download | BSI Compliance Navigator](#)
  - [Events for your calendar](#)
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Discover what you need to know about Notified Body and Approved Body certification and MedTech legislations!

To know more, visit our dedicated

BSI IVD team has just released a new brochure. Take a look and discover our IVD team expertise, products covered and relevant information to comply with requirements and increase your market readiness.

For additional resources visit our dedicated [IVD](#) and [IVDR](#) webpages!

[View Brochure](#)

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## Ethical and Trustworthy Artificial Intelligence

As the AI technology rapidly evolves, so does the regulation governing its use.

When it comes to navigating the AI regulatory landscape and placing your device on the market, proactivity and readiness are essential.

To help you navigate the complex AI regulatory landscape, we have created a dedicated whitepaper:

Ethical and Trustworthy Artificial intelligence - BSI's introduction to the European Artificial Intelligence Draft Act (AIA).

[Download the Whitepaper](#)

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## On demand webinar - Pathways to IVDR Compliance

Listen back to our extended webinar to hear subject matter extendedexi.7 (i) (i)12 H(s)-2( )JEMof48 19.

understanding of the status related to high-risk CDx & Class D devices.

The webinar included:

- 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



