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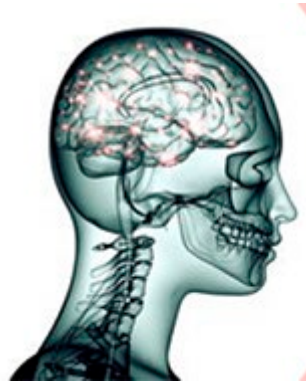

Regulatory review

Your monthly medical device update

May 2023

Featured in this Newsletter

BSI Medical Devices presents: Guide to Conformity

This video helps you navigate the conformity journey to place your product on the market. It also provides an overview of medical devices and IVDs regulatory framework, as well as BSI Regulatory Services offering for QMS and product certification.

Discover what you need to know about Notified Body and Approved Body certification and MedTech legislations!

To know more, visit our dedicated webpage.

MHRA announces additional extension for UKCA standstill period

The MHRA recently announced an additional twelve-month extension to the current standstill period to comply with UKCA marking regulations.
From 1st July 2025, legislative transitional arrangements will apply for placing Medical Devices and IVDs on the Great Britain market.

To know more visit our UKCA dedicated webpage
Further guidance can be found at GOV.UK dedicated webpage

BSI issues its first certificate for an IVD Companion Diagnostic (CDx) device under the IVDR

Full scope Notified Body BSI The Netherlands (2797) is pleased to announce the issue of its first CDx certificate under the In Vitro Diagnostics Regulation (IVDR (EU) 2017/746).

The certificate is issued to Invivoscribe, Inc. for the LeukoStrat® CDx FLT3 Mutation Assay, a qualitative, PCR-based in vitro diagnostic test, intended to assist with making treatment decisions for patients diagnosed with acute myelogenous leukemia (AML), with FLT3 ITD and TKD gene mutations.

Read More

New In Vitro Diagnostic brochure available

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

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

On demand webinar - Pathways to IVDR Compliance

Listen back to our 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 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

Watch on demand webinar

Open doors for NBOp (Notified Body Opinion) under MDR Article 117

Are you looking for a NBOp (Notified Body Opinion) under MDR Article 117?

BSI was the first ever Notified Body to issue a NBOp for a drug-device combination product.
The Medicinal and Biologics Team is open for Article 117 applications!

To know more, take a look to our MDR Article 117 dedicated brochure:

MD Article 117 Brochure

Latest white paper is available for download | BSI Compliance Navigator

With the date of application for the MDR and the IVDR having now passed, this updated paper is intended to assist manufacturers with legacy products on the market with certificates of conformity to the Directives to assess their plans to transition to the regulations. It is also intended to assist manufacturers entering the EU market with devices for the first time under the regulations.

Read the full white paper, which has been updated by Eamonn Hoxey, Director, E V Hoxey Ltd, Cirencester, UK.

Download Now

Click here to start your free trial of Compliance Navigator today.

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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