Medical Devices Newsletter View Online

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Newsletter

Medical Devices Newsletter

January 2025

Welcome to the January edition of our Medical Devices Newsletter. This month, we bring you the latest updates, insights, and developments in the medical devices industry and regulatory updates. Dive in to stay informed and ahead in this ever-evolving field.

Visit our dedicated webpage

Survey on the monitoring of availability of medical devices on the EU market

The EU Commission released the second survey round to support the monitoring of the availability of medical devices on the EU market in the context of the implementation of regulations on medical devices and IVDs.

BSI encourages medical devices and IVDs manufacturers, authorised representatives, importers and distributors to take the survey. Your feedback is pivotal to support the decision-making process of EU medical device regulators.

Complete the survey now

Structured Dialogue with BSI

BSI has been offering Structured Dialogue for over 20 years while fully respecting the independence and impartiality of the Notified Body.

Whether you're looking to discuss high-level aspects of evidence of conformity, Notified Body assessment procedures, QMS requirements, or more complex combination of clinical, technical, and regulatory conformity approaches, request Structured Dialogue with BSI today.

Visit our webpage

Software as a Medical Device

As an SaMD manufacturer, it's essential to ensure your product meets all regulatory requirements before market launch.

Choosing an EU Notified Body or UK Approved Body with industry expertise is crucial. Here at BSI, our dedicated SaMD team has deep knowledge in AI, software development and cybersecurity and is ready to walk you through your conformity journey.

Take a look at our SaMD brochure and webpage.

Visit our dedicated webpage

Best Practice Guidelines for Article 117 Documentation Submission

Navigating the complexities of Article 117 of the MDR? BSI has released the Best Practice Guidelines for Article 117 Documentation Submission, a comprehensive guide designed to streamline the submission process.

Head over to our dedicated webpage to find out more.

Find out more

Guide to Conformity Series - CE marking

Watch chapter 3 of our Guide to Conformity Series - CE marking.
Stay tuned for the upcoming chapters.

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

Watch the video now

Published recommendations suggest path to fairer and safer medical AI

The **STANDING Together** initiative has published internationally agreed recommendations in top medical journals, including **The Lancet Digital Health**, aiming to reduce bias in medical AI technologies and improve their fairness.

Co-authored by BSI's Vishal Thakker, the guidance emphasizes using diverse, inclusive **datasets** and identifies potential biases to build AI healthcare technologies.

Experts from 58 countries, led by the University of Birmingham, aim to make medical AI safer and more equitable, ensuring benefits reach all patient communities.

Details here

Preparing for certification in 2025?

BSI Compliance Navigator is an online document management platform containing over 7500 essential standards, guidance and regulatory documents required for certification in the EU, UK, US and MDSAP countries.

Request a free 30-day trial today

Events for your calendar

Complement ISO 42001 – Integrate AI-specific considerations into other management frameworks

Wednesday, 12 February 2025 | 09:00 & 16:00 GMT

This webinar provides an overview of how organizations can integrate AI specifications in their existing management systems and create a more comprehensive framework to address security, risk, and ethical considerations of AI in a cohesive manner.

Register for webinar

2025 Combination Products in the EU

28-29 January 2025 | Brussels, Belgium

Join us on 28-29 January 2025 at the Radisson Grand Place in Brussels for the DIA and RAPS summit. BSI will present on key topics including Rule 14 & Rule 21 guidance, conformity assessments, and Structured Dialogue for medical devices and IVDs. Don't miss insights from Jonathan Sutch and the Medicinal and Biologics team!

Details here

17th Annual Pre-Filled Syringes and Injectable Drug Devices Conference

January 14 - 16 2025 London, UK

Join BSI's expert Arabe Ahmed, Medicinal Technical Specialist on this insightful panel discussion: Navigating the Regulatory Landscape for Pre-Filled Syringes and Injectable Drug Devices.

Details here

Visit our webpage

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