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Regulatory review

Your monthly medical devices update

December 2024

Featured in this Newsletter

Dr Manuela Gazzard's, President Regulatory Services, end of year message

Dear Valued Client,.

With 2024 coming to a close, we want to take a moment to reflect on what has been an exciting and transformative year for Regulatory Services. Our team has continued to refine and expand our offerings,

ensuring we stay aligned with our clients' evolving needs.

We are proud to share that in order to serve our clients and stakeholders more holistically we have made some organisational changes. All conformity assessment services are now within one global division. This includes new horizontal services such as the new EU Artificial Intelligence act adopted on 13 March 2024.

Through these changes we will be able to conformity assess products in need of several compliance schemes coordinated and communicate with our regulators in a more streamlined way. With now over 1,600 highly talented professionals, we are committed to serve you at the forefront of innovation.

Highlights from 2024 include:

- Med Dev & IVD Milestone: In November, we achieved a significant milestone by issuing over 2,000 certifications under the MDR and IVDR.
- AI Leadership: In October, we issued our first AI ISO 42001 certification to KPMG Australia, demonstrating our leadership in this emerging sector. Additionally, DeepEyeVision Inc. in Japan became the first organisation to benefit from BSI's AI algorithmic auditing and dataset testing services.
- Product Certification: Innovation and sustainability remain central to our strategy. A prime example is GSK's Kitemark certification for Minimized Risk of Antimicrobial Resistance, which evaluates the antibiotic manufacturing processes to support combatting increasing resistance.

Looking Ahead

As we prepare for 2025, we are excited to continue working with you navigating the challenges and opportunities in a dynamic and increasingly complex regulatory environment.

Thank you for your trust and partnership.

On behalf of my colleagues, I wish you, your families, and your loved ones a healthy and happy New Year.

Warm regards,
Dr Manuela Gazzard President,
BSI Regulatory Services

Structured Dialogue with BSI

BSI has been offering Structured Dialogue for over 20 years to enhance the efficiency and predictability of the conformity journey through all its phases, while fully respecting the independence and impartiality of the Notified Body.

Whether you're a start-up, an SME or a well-established manufacturer, get in touch to discover how BSI Structure Dialogue can fit your conformity journey.

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

Read the brochure

Understanding Article 16(4) Certification

Are you an importer or distributor in the EU undertaking relabelling or repackaging activities for medical devices? Do you know that MDR and IVDR require you to get an Article 16(4) certification to demonstrate your QMS complies with the regulations requirements for these activities?

To know more visit our dedicated webpage.

Visit our dedicated webpage

Enhancing Trust and Security: Introducing Digital Seals for MDR, IVDR, and UKCA Certificates

Here at BSI, we are focused on solving our clients' biggest challenges by providing new methods and technology that promote deeper trust, sustainability, and security.

To enhance the security of your certificates with the latest innovation, we are introducing digital seals for MDR, IVDR and UKCA certificates.

Read our e-news

BSI Compliance Navigator

230 new documents were added to the Compliance Navigator platform in Q3 2024

That takes the total number of new documents added in 2024 to 696 and over 7500 now in total. Documents added include standards from BSI, ASTM, CLSI as well as guidance documents from the FDA, Gov.AU and MDCG

Download the list of new documents **here**.

To find out more about the entire content set and how you could benefit from access to Compliance Navigator, request a free trial below.

Request more information

Events for your calendar

AI Algorithm Auditing and Dataset Testing (AA&DT) for the Medical Imaging Industry

Thursday, 16 January 2025 | 09:00 &16:00 GMT

Join this insightful webinar as you learn about the relationship of this voluntary assessment service to the full conformity assessments required under the EU AI Act, and the benefits that a voluntary assessment can offer.

Register for webinar

PFAS phase out and its impact on Medical Devices

Wednesday, 29 January 2025 | 09:00 and 16:00 GMT

The EU is proposing a full ban on per- and polyfluorinated alkyl substances (PFAS) by 2030, expected to affect many medical devices which use PFAS within the device or part of the manufacturing process. In the webinar we will introduce the EU restriction proposal and the impact it may have on medical devices.

Register for webinar

On Demand Webinars

- Implement ISO 42001 – Demonstrate a commitment to ethical and responsible AI use
- Article 16(4) Certification Scheme

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