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Regulatory review

Your monthly medical devices update

February 2024

Featured in this Newsletter

Nanomaterials and nanotechnology in medical devices

Check out our new leaflet on nanomaterials and nanotechnology. Learn more on their application in the medical devices industry and access state of the art guidance.

Download now

Orthopaedic and Dental Medical Devices

Our Orthopaedic and Dental Team has just released a new brochure. Check out the O&D dedicated webpage to discover more.

Visit now

Press Release: EU Commission proposal as regards transitional provisions for certain IVDs

On 23 January 2024, the EU Commission released a proposal as regards the transitional provisions for certain legacy IVDs by providing manufacturers and notified bodies with additional time, under certain conditions, to complete applications and necessary conformity assessment procedures.

The Commission is also proposing measures to enable a gradual roll-out of EUDAMED modules already available for voluntary use and new requirements on prior notice for disruption of supply of certain medical devices and IVDs. To know more read our press release here:

Read the press release

BSI Compliance Navigator

Both Medical Device Regulations (MDR & IVDR) state in Article 10, section 4, that "the technical documentation shall be such as to allow the conformity of the device with the requirements of this Regulation to be assessed. The technical documentation shall include the elements set out in Annexes II and III".

Click the button below to download the latest BSI whitepaper - Technical Documentation under the Medical Device and In Vitro Diagnostic Regulations (MDR and IVDR).

Download now

Events for your calendar

Webinar - Shaping Trust in AI: A global perspective on the impact of the EU AI Act

Tuesday 27 February 2024

Join this informative webinar to hear BSI's AI subject matter experts discuss detailed updates on the EU AI Act progress, covering its history, the significant elements of the recent December deal, and its potential impact on various industries.

AM webinar: 9.00 - 10.00 GMT

PM webinar: 16.00 - 17.00 GMT

Register now

Webinar - Navigating your IVDR certification process for CE marking: How to work with your Notified Body for a sleek process

Tuesday 19 March 2024

Join us for this webinar to gain a better understanding of the IVDR certification process to obtain CE marking for In vitro Diagnostics medical devices in Europe. We will also share our key learnings to help you work with Notified Bodies more efficiently during your application and review processes. Register for one of two time slots on Tuesday 19 March 2024.

AM webinar: 9.00 - 10.00 GMT

PM webinar: 16.00 - 17.00 GMT

Register now

The 8th EAAR Annual Conference on New Medical Device Regulations

26 - 27 February, 2024, Brussels, Belgium

Organized by the European Association of Authorised Representatives, EAAR is the platform for all stakeholders across the medical and IVD medical devices landscape. With a dedicated focus on the challenges faced by manufacturers and other stakeholders in embracing the EU MDR and IVDR.

Speaker: Alex Laan, February 27, State of Play Notified Bodies (IVDR)

Details here

KIMES 2024 - 39th Korea International Medical & Hospital Equipment Show

14 - 17 March, 2024, COEX Exhibition Venue, Seoul, Korea

KIMES provides the opportunity to identify and confirm the great potential and prospects of the future medical industry as well as the latest medical industry trends as a venue where 1,200 domestic and overseas manufacturers show new technology and new products. It will become the venue for communication to present the latest medical information and technology to keep up with the fast-developing medical market.

BSI will be exhibiting at KIMES! Come visit our D820 and learn from our leading experts during our seminar.

Details here

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