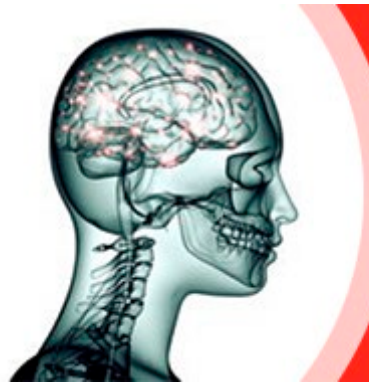
Contact us
+49 69 2222 8 9200
marketing.de@bsigroup.com



Regulatory review

Your monthly medical device update
September 2021

Featured in this Newsletter

IVDR Classification

The In Vitro Diagnostic Regulation (IVDR) (EU) 2017/746 is the new EU legislation applicable to in vitro diagnostic (IVD) medical devices. Entering into force on the 25 May 2017 marking the start of a five-year transition period for manufacturers and economic operators, the IVDR replaces the EU In Vitro Diagnostics Directive (IVDD) 98/79/EC.

Manufacturers wishing to apply to a notified body for a conformity assessment of their IVD medical device have until the Date of Application of the IVDR in May 2022 to update their Technical Documentation to meet the requirements and comply with the new, more stringent Regulation.

All devices will need to be divided into classes. This classification map will allow you to allocate your device correctly under the IVDR.

Download the IVDR classification rules

General Medical Devices Brochure

Our General team of highly trained technical specialists are product experts who work with device manufacturers and understand the specifics of complex medical devices.
The team has an average of 20 years' industry and regulatory experience, and we are able to provide conformity assessments under the EU MDR and UK MDR (2002).

General Medical Devices Brochure

Listen back to our most recent webinar - MDR Rule 14 Devices conformity assessment process and documentation requirements for submissions

The MDR Rule 14 Devices – conformity assessment process and documentation requirements for submissions webinar was presented by Theresa Jeary, Medicinal Expert, BSI. The webinar looked in detail at the conformity assessment process for medical devices containing an ancillary medicinal substance.

If you missed the webinar or were not able to join you can view the recording and presentation slides here.

Upcoming Webinar - What you need to know about the Periodic Safety Update Report (PSUR) & Vigilance under the Medical Device Regulations

Join BSI's Richard Holborow, Head of Clinical Compliance, to hear about important insights into what you need to know about the Periodic Safety Update Report (PSUR) and vigilance under the Medical Device Regulations. Richard will also be joined Simon Lidgate, Clinical Team Manager (Active Implantable), BSI.
The webinar is open to everyone and is particularly suitable for those individuals who are involved in post market surveillance activities for their organisation.

Participants will gain a better understanding of the post market requirements as listed under Articles 86 and 87 of the MDR and will be able to confidently know which information is required for the PSUR and which vigilance events are reportable.

Please join us for this insightful webinar and choose from one of two sessions:

Wednesday 29 September: 10.00 – 11.00 CEST **Register now**
Wednesday 29 September: 17:00 – 18:00 CEST **Register now**

Digital pre-applications for CE marking, UKCA and QMS services

We are pleased to hear initial feedback for our new digital pre-applications portal for CE marking, UKCA and QMS services. The portal will allow you to access the pre-application process through a digital interface, and it replaces our Company Information Forms.

Feedback includes:

"Transparency and oversight of current and previous applications, more accurate CIF completion, saving time in the overall process and the flexibility to allow different users to update the information."

"Puts the Manufacturer in control of their applications."

"Visibility of the history of applications and overview of the status".

Complete the form

Events for your calendar

BSI at RAPS Switzerland Chapter virtual event, 30 September

BSI's IVD expert, Dr Heike Möhlig-Zuttermeister, will speak at the next RAPS Switzerland Chapter virtual event on the topic "IVDR: key lessons learned so far" and outline what we have learned so far from a notified body perspective. Register for this free webinar on 30 Sept at 12:00 CEST.

Find more information here

BSI at VDE online event about Agile Development of Medical Software, 5 October

Agile software development has become state of the art in many companies. Due to the more flexible development style, the question sometimes arises whether it is too flexible to meet the strict regulatory requirements for medical devices. This event offers different views on (successful) agile medical software development. Hear BSI's Bryan Pourciau, technical expert for AIMD, who will give a Notified Body's perspective.

Find more information here

BSI at LISAVienna MDR & IVDR Regulatory Konferenz, 12 October in Vienna, Austria

This is the fifth regulatory conference on regulatory requirements for marketing authorisation of medical devices and in vitro diagnostics in Europe, which will take place in Austria's capital Vienna. Internationally recognised experts from the relevant fields will participate in the programme. Join us in Vienna to hear a session on performance evaluation under the IVDR presented by BSI's IVD expert, Dr

Heike Möhlig-Zuttermeister.

Find more information here

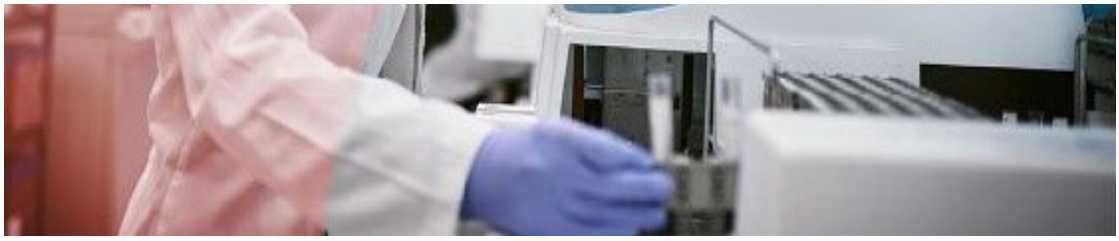
BSI at Swiss Medtech MDR & IVDR conference, 19 October in Bern, Switzerland

The focus of the MDR & IVDR Annual Conference is "Switzerland as a Third Country". You can expect a varied programme with two plenary sessions, panel discussions, networking and six breakout sessions, each with a thematic focus. BSI's IVD expert, Dr Heike Möhlig-Zuttermeister, will present on performance evaluation and clinical evidence under the IVDR in one of the breakout sessions.

Find more information here

Find out the latest information about BSI Medical Devices Events and Conferences.

UDI and the EU Regulations | New whitepaper published



The latest free medical devices whitepaper provides an overview of the EU UDI system, its requirements and the status of EUDAMED, along with some practical recommendations for manufacturers to support their UDI system compliance efforts.

Download whitepaper

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