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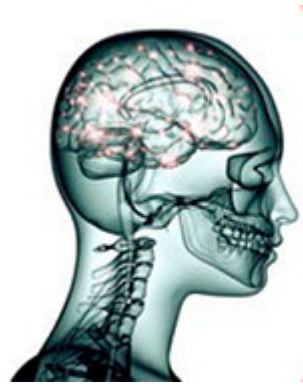


Regulatory review

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: 09.00 – 10.00 BST **Register now**
Wednesday 29 September: 16:00 – 17:00 BST **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:

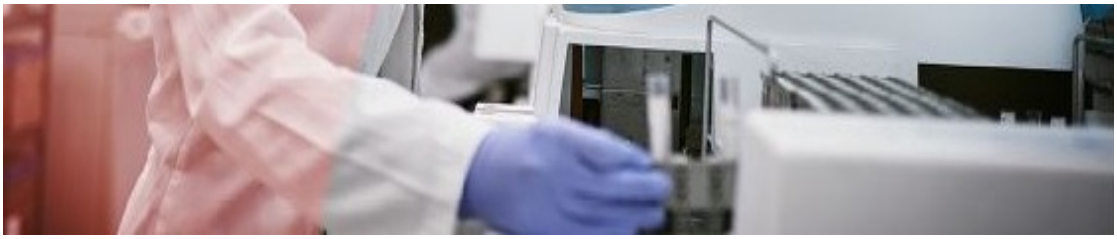
"Transparency and oversight of current and previous applications, more accurate CIF completion, saving time in the overall process and the flexibility to allow different users to update the information."

"Puts the Manufacturer in control of their applications."

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

Complete the form

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

Events for your calendar

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

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