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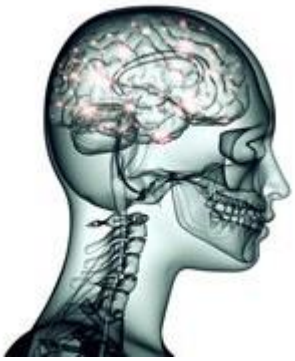

Regulatory review

Your monthly medical device update

January 2019

Happy New Year from BSI

We're looking forward to a busy 2019 as we end the ISO 13485:2016 transition and continue working towards MDR and IVDR designations.

To kick off the new year, here's your news round-up for the month including new guides on MDR documentation submissions and Notified Bodies, news about our newly-formed Medicines and Biologics team, and two webinars for you to join.

MDR documentation submissions guide

The two most frequent reasons for delays to technical documentation reviews are:

- BSI has not been provided with all the information needed for the review
- The information is present within the technical documentation but is difficult to locate.

To reduce the frequency of these issues, we have created the BSI “MDR Documentation Submissions: Best Practices Guidelines”.

Read now

A new BSI Guide to Notified Bodies

Do you want to know more about the role of the Notified Body? The new BSI Guide to Notified Bodies provides a detailed overview, covering areas including where the CE mark applies, the role of the Competent Authority and the process a manufacturer has to go through to get a CE mark.

Read now

There’s still time to register for our Implant Card webinar

Thursday 24 January, 4pm GMT

Does your device require an implant card under the Medical Devices Regulation (MDR)? The Regulation brings with it a number of new requirements, including the requirement for implantable devices to come with an implant card, which is given to the patient and includes important information such as device name, its physical properties and intended use.

Join our webinar on Thursday 24 January to learn more about the requirements from **Kevin Madden, BSI Orthopaedic and Dental Technical Specialist Training Lead & Technical Team Manager**.

Register now

Register for our Medicines and Biologics Webinar

Tuesday 26 February, 4pm GMT

We're delighted to announce the formation of a new technical CE Conformity Assessment team at BSI that will focus on Medicinal Products & Biologics. Next month we'll be running a webinar where our newly-appointed **Global Head, Medicinal & Biologics Team, Dr Jennifer Durrant**, will be speaking about the new team and introduces the advantages this will provide to our clients.

Register now

New European Commission documents

The Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs has launched a campaign to inform as many stakeholders as possible about their roles and responsibilities under the new Regulations. A series of factsheets and step-by-step guides is available:

- Factsheet for Authorities in non-EU/EEA States
- Factsheet for Manufacturers of In Vitro Diagnostic Medical Devices
- Factsheet for Authorised Representatives, Importers and Distributors
- Factsheet for Manufacturers of Medical Devices

- Transition Timelines from the Directives to the Regulations

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