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Regulatory review

Your monthly medical device update
January 2020

Happy 2020!

It's going to be another busy year with the MDR transition deadline approaching and lots more happening in the Medical Device industry. Here is your round-up for January as we look forward to another exciting year ahead.

BSI Netherlands Notified Body designated to the In Vitro Diagnostic Regulation (IVDR)

Following the recent announcement that our UK Notified Body (0086) was the first to achieve full-scope designation to the new IVDR (EU 2017/746), we are now also delighted to announce that our Netherlands Notified Body (2797) has been designated to the Regulation, covering all devices specified under the Implementing Regulation (EU) 2017/2185 for IVDR.

Read more

The MDR date of application is less than five months away – are you prepared?

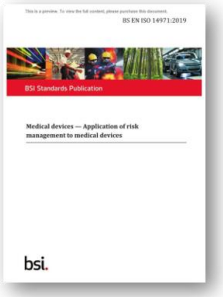
The Medical Device Regulation (MDR) has brought with it many new requirements for manufacturers to meet to achieve the CE mark for their devices. Use our resources as you manage your transition:

- MDR certification process
- Conformity assessment routes guide
- Frequently asked questions
- Readiness review
- Mapping guide
- Best practice documentation submissions

All resources

Now published: ISO 14971:2019 Medical devices. Application of risk management to medical devices

Recognized by regulatory authorities in the US, Canada, Europe and more, this international standard helps medical device manufacturers establish, document and maintain a systematic risk management process across all phases of the lifecycle of a medical device. Use of the standard helps streamline the regulatory processes that enable entry to selected markets.



Read more

Join us at the BSI EU IVDR Spring 2020 Roadshow

The BSI EU In Vitro Diagnostic Regulation (IVDR) Roadshow will soon be returning to various locations across Europe.

Come along to hear the latest IVDR updates from BSI and engage face-to-face with the only organization with two Notified Bodies with full scope designation to the IVDR.

- Munich, Germany – 18 February 2020

- London, UK – 3 March 2020
- Amsterdam, Netherlands – 25 March 2020

Register your interest

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