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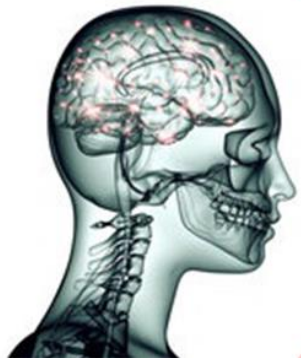


Regulatory review

Your monthly medical device update
February 2019

BSI achieves successful Medical Devices Regulation (MDR) designation in the UK

We are delighted to announce that the MHRA has confirmed BSI is now designated to the MDR (EU 2017/745) in our market leading UK Notified Body (0086). BSI is the first Notified Body to achieve this significant milestone and has been designated for the full scope we applied for in November 2017. Full details can be found on the NANDO information system:

We believe this is a fantastic step in our MDR journey together with our clients and will very shortly confirm when we will commence taking applications to the MDR.

More about MDR

ISO 13485:2016 transition countdown

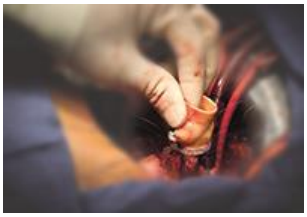
The deadline for the ISO 13485:2016 transition period is fast approaching. Manufacturers must meet the requirements of ISO 13485:2016 by **28 February 2019** to maintain their certification. If this applies to you, we very strongly recommend you review your transition plan for ISO 13485 immediately. Contact us now or visit our website for materials to support your transition.

View support materials

Register for our Medicines and Biologics Webinar

Tuesday 26 February, 4pm GMT

There's still time to register for our webinar this month on Medicinal Products & Biologics. Dr Jennifer Durrant, Global Head, Medicinal & Biologics Team, will be speaking about this newly-formed technical CE Conformity Assessment team at BSI and the advantages it will provide to our clients.



Register now

New European Commission documents (continued)

The Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs has launched a campaign to inform stakeholders about their roles and responsibilities under the new Regulations. A series of factsheets and step-by-step guides is available. We shared some of these in January, and here are some others you might find useful:

- Implementation Model for in vitro Diagnostic Medical Devices Regulation - Step by Step Guide
- Implementation Model for Medical Devices Regulation - Step by Step Guide
- Factsheet for the Procurement Ecosystem of Medical Devices and in vitro Diagnostic Medical Devices
- Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) - infographics

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