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Regulatory review

Your monthly medical device update
November 2019

Double designation celebrations for BSI – Netherlands Notified Body is designated to the MDR and UK Notified Body is designated to the IVDR

We are delighted to announce that we have achieved our second full-scope designation to the MDR for our Netherlands Notified Body (2797), enabling us to ensure continued access to the European medical devices market for our clients. This follows on from our UK Notified Body (0086), which was the first to achieve full-scope designation to the MDR at the start of 2019 and, more recently, the first in the world to issue an MDR product certificate to a client.

We are also delighted to announce that the MHRA recently confirmed our UK Notified Body as one of the first in Europe to be designated to the new IVDR (EU 2017/746). Our UK Notified Body is also the first to achieve full-scope designation, which covers all devices specified under the Implementing Regulation (EU) 2017/2185 for IVDR.

Dr Manuela Gazzard, Group Director, BSI Regulatory Services, celebrates our designations as being

"testament to the dedication, expertise and skills of our people," helping to ensure both BSI and our clients remain resilient to the challenges ahead.

Watch videos

New white paper: The impact and potential for 3D printing and bioprinting in the medical devices industry

3D printing refers to a set of manufacturing processes which all build components using an additive approach. Download this white paper for:

- A review of the history of 3D printing of medical devices
- Discussion of the key characteristics of this technology's successful exploitation
- Examination of the scope for bioprinting processes to enhance medical devices, bearing in mind the lessons learnt from the more established 3D printing industry.

Download white paper

Join our webinar on Article 120 (3) – What is due in 2020?

Wednesday 4 December 2019, 4.00pm GMT

Join Suzanne Halliday, Regulatory Director and Head of Notified Body to find out what manufacturers need to think about in 2020 to meet the requirements of Article 120 (3). The webinar will cover:

- Significant changes in the design or intended purpose
- Post-market surveillance
- Market surveillance
- Vigilance
- Registration of economic operators
- Registration of devices

Register now

Join our webinar on Symbols to be used on labelling (ISO 15223) and Information to be provided by the manufacturer (ISO 20417)

NEW DATE:* *Tuesday 25 February 2020, 4.00pm GMT

Register now to hear from BSI's Dr Peter Bowness, Medicinal and Biologics Technical Team Manager, about the recently updated ISO 15223 on symbols to be used with medical device labels, and the recently developed ISO 20417 covering information to be provided by the manufacturer.

Register now

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