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Regulatory review

Your monthly medical device update

June 2019

BSI to begin accepting applications for MDR

We can confirm that BSI is now accepting applications under the MDR for our UK Notified Body (0086).

BSI UK Notified Body (0086) will begin to process quote requests and schedule work over the coming months. BSI will provide conformity assessments to the full scope of the MDR. This service will focus on our existing UK (0086) and NL (2797) clients. For further details on BSI's scope, please visit the NANDO information system.

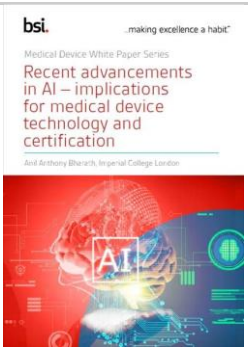
Who can I contact for further information?

Please contact your Account Manager to initiate the quotation process. They will be able to answer your questions in the first instance, and we recommend you visit our dedicated website for your MDR Transition.

Find out more

Read our latest white paper on Artificial Intelligence

A system whose behaviour is impossible to guarantee seems unsatisfactory from a safety or regulatory perspective. To appreciate why components that incorporate artificial intelligence (AI), and specifically, machine learning, might even be considered, it is helpful to gain a little bit of insight into how modern AI systems are being built, and why they are changing the way in which complex software systems are being engineered.



Download BSI's white paper and get an overview of where AI is being used in healthcare, and why it might be increasingly seen in medical devices, considering what specific additional requirements this might place on regulatory requirements in the near future.

Download white paper

Are you an IVD Manufacturer? Please take a few minutes to complete our survey

We recently conducted in-depth interviews with 49 In-Vitro Diagnostic (IVD) Manufacturers and found out that over 50% were not yet prepared to meet the requirements of the IVD Regulation (IVDR).

The IVD industry is undergoing significant change and BSI is committed to ensuring a smooth transition for all clients wishing to certify to the IVDR. If you're an IVD Manufacturer we'd like to hear about your transition plans so we can ensure our service will be ready to meet your requirements.

Complete survey

Upcoming events

Will you be joining us?

MedTech Summit, Brussels – *17-21 June 2019*

Talks will include 'EU Medical Device Regulations, Notified Body overview and update from BSI' by Jayanth Katta, Regulatory Lead at BSI. Use code **CQ7132BSI** for an exclusive 25% discount*.

Register now

AAMI/BSI Conference, Heathrow – *27-28 June 2019*

Join regulators and standards leaders from around the world to hear about some of the latest developments in Medical Devices.

Register now

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