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Regulatory review

Your monthly medical device update
October 2019

BSI certifies first product to the Medical Devices Regulation

We are delighted to announce that BSI certified the first product to the Medical Devices Regulation (EU 2017/745) via our UK Notified Body (0086) last month.

Being the first to deliver a conformity assessment under the new Regulation is evidence of the hard work, dedication, skills and expertise of our people.

Gary Slack, Senior Vice-President of the Notified Body at BSI, said: "The transition to the MDR is a significant challenge to the medical device industry as a whole. We continue to work towards certifying more devices under the MDR to the tight timelines outlined in the Regulation."

Read full article

New white paper: Risk management for medical devices and the new ISO 14971

Risk management is an important aspect in the development of medical devices. Patients are already in a vulnerable position and, during diagnosis and treatment, they should be protected from risks that could further impact their health.

Discover how regulations and standards for medical devices have developed over the recent decades, including the risk management process as described in ISO 14971 and the main changes in the third edition.

Download white paper

Where are you in the medical device product lifecycle?

An understanding and consideration of the complicated clinical and regulatory requirements early in the product lifecycle could ensure your company gains the competitive advantage needed to bring a product to market.

Watch our video to find out how we can support you at each stage of the lifecycle.

Watch video

Access standards to support your US medical device compliance processes

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We are pleased to announce that a collection of 60 AAMI standards has been added to Compliance Navigator.

Together with the existing collection of 150 ASTM medical device standards, these AAMI standards will support subscribers' compliance processes to US requirements.

Request more info

Events for your diary

BSI EU In Vitro Diagnostic Regulation (IVDR) Roadshow – Berlin

22 October 2019

Join us to hear about some of the most significant changes to the European Regulatory and Compliance Expectations for CE marking.

Learn more

American Medical Device Summit 2019 – Chicago, USA

28-29 October 2019

A senior level medical device event exploring trends in development, quality management, speed to market, manufacturing and life-cycle management.

Learn more

Medica – Düsseldorf, Germany

18-21 November 2019

BSI will be teaming up once again with CSA Group, who provide product certification and product testing services to Canada, the US, Europe, and worldwide.

Learn more

US Med Tech Summit – Chicago, USA

19-20 November 2019

Bringing together industry, Notified Body experts and FDA insight, to share the very latest on EU MDR implementation, FDA policy and digital health.

Learn more

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