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Regulatory review

Your monthly medical device update

November 2018

BSI Netherlands Successfully Achieves Designation as a Medical Devices Notified Body

13 November 2018

BSI is delighted to formally announce our successful designation under the 3 Medical Device Directives (MDD, AIMDD and IVDD) in the Netherlands. These designations represent a significant milestone in our Medical Device Regulatory activities and more than two years of work in achieving this milestone. This firmly anchors BSI's presence as a Medical Devices Notified Body irrespective of the BREXIT outcome.

Read the full statement

Do you know which services BSI can offer you?

Download our new brochure to find out why we are a trusted, world-class Notified Body dedicated to providing rigorous regulatory and quality management reviews and product certifications for medical device manufacturers — around the



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Dow nload now

Does your device require an implant card under the MDR?

The Medical Devices Regulation brings with it a number of new requirements, including the requirement for implantable devices to come with an implant card. Implant cards are given to the patient and include some important information about the device, including device name, including its physical properties and its intended use.

Join us on Thursday 29 November at 4pm GMT for our webinar and learn more about the requirements from Kevin Madden, BSI Orthopaedic and Dental Technical Specialist Training Lead & Technical Team Manager.



Register now

BSI and CSA Group at Medica 2018



BSI and CSA Group joined over 5000 exhibitors at Medica in Germany, the world's largest event for the medical sector. Our teams used our expertise and knowledge to share information on services to help you reduce costs of delayed product launches and get your devices to patients and healthcare professionals all over the world. Visit our website to find out more.

Find out more



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