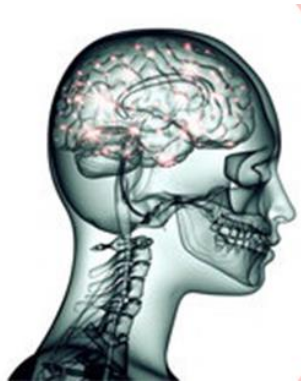
Email not displaying correctly?
View it in your browser

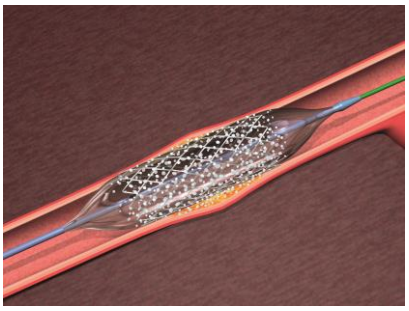
Contact us
+44 345 080 9000
eu.medicaldevices@bsigroup.com



Regulatory review

Your monthly medical device update
April 2019

New Technical team: Medicinal and Biologics



We're delighted to introduce our new technical CE Conformity Assessment team focusing on Medicinal Products and Biologics.

Dr Jennifer Durrant heads up the team, who are experienced in drug development, quality by design, good manufacturing practice systems and controls in addition to interactions with Competent Authorities. They will be valuable in supporting Medical Devices containing or used with medicinal substances.

Meet the team

Will you be attending MedTech Summit 2019?

Our Notified Body Regulatory Lead, Jayanth Katta, will be speaking at the interactive sessions on Monday 17 June and presenting on **EU Medical Device Regulations, Notified Body overview and update from BSI**.

View agenda

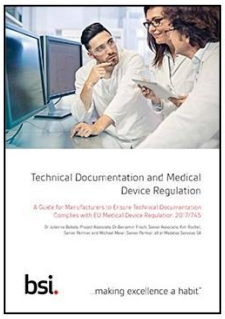
Join our webinar on IVDR Readiness

Wednesday 29 May 2019

Are you an IVD device manufacturer? Register to join our webinar where Erica Conway, BSI's Global Head – In Vitro Diagnostics, will discuss the IVDR Readiness Review which can facilitate your internal preparation and be used as a useful tool for planning your transition strategy.

Register now

White papers for you to download



Technical Documentation and Medical Device Regulation

This white paper explores the regulatory requirements for Technical Documentation and gives some insight into what will be expected under the new Medical Device Regulation (MDR). Download your copy now and use this as part of your comprehensive toolkit to plan for the new Regulation.

Download your copy

General Safety and Performance Requirements in the new MDR

This paper provides comparison of the Safety and Performance Requirements (SPRs) of the MDR and the Essential Requirements (ERs) of the Medical Devices and Active Implantable Devices Directives that they replace, allowing you to understand the changes in more detail.

Download your copy

bsi.

...making excellence a habit.™