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July Medical Device Newsletter, 2016

EU referendum result

On Thursday 23rd June, 2016, the UK voted to leave the EU.

Following the vote, BSI will continue to operate as an EU Notified Body during the UK's withdrawal from the EU. We anticipate that there will be no major operational change to our business thereafter.

Visit our website to read the full statement.

MEDDEV 2.7.1 Revision 4

On July 1st, the EU Commission released MEDDEV 2.7.1 Revision 4. This guidance file, which provides information for manufacturers on clinical investigations and evaluations, has been revised with a number of clarifications and some new requirements.

We have created a guide which outlines the major changes to help you understand how this impacts you. The guide discusses the new requirements, and highlights where there has been clarification of existing requirements.

Download the Top 10 Changes now and consider the implication on your clinical evaluations.

New BSI white paper - IVD Regulation

BSI's new white paper "How to prepare for and implement the upcoming IVDR – Dos and don'ts", is now available for download.

The magnitude of the changes affecting the IVD industry requires thorough understanding, robust plans and prompt action. Read this white

Download guidance

Complimentary webinar - MEDDEV 2.7.1

New version of MEDDEV 2.7.1 - Revision 4: Key changes and clarifications - 18th October 2016

BSI will host a complimentary webinar to discuss the key changes and additions to MEDDEV 2.7.1 Revision 4. This will supplement the guidance document, exploring the clarifications made in the guidance, as well as the new requirements.

Join Monisha Phillips, Global Head of the Orthopaedic & Dental Team at BSI, and Amie Smirthwaite, Product Technical Expert, for this webinar, which will highlight the areas you need to be aware of when planning and conducting a clinical evaluation.

Sign up now

Radio Equipment Directive (RED)

We're accredited!

The Radio and Telecommunications Terminal Equipment (R&TTE) Directive has been replaced by the new Radio Equipment Directive (RED). The Directive covers equipment including medical devices with wireless modems, communication with implantable sensors and programming of implantable devices.

After entry into force of the new Radio Equipment paper to understand more about the changes you face.

Download your copy

NEW complimentary webinar

In Vitro Diagnostics Regulation – Changes to the IVD regulatory landscape – 9th August 2016

Significant changes are coming in the IVD industry with the new IVD Regulation, not least with the increase in manufacturers who require a notified body. Manufacturers must be aware of how the new Regulation will impact their business.

Join Erica Conway, Global Head of the IVD Team at BSI, to learn about the major changes that will impact the IVD industry.

Sign up to the webinar today.

Directive in June 2016, **BSI can announce that we have been accredited** to certify against the Directive under Annex IV, Full Quality Assurance.

BSI has over 10 product specialists with expertize with devices covered by the RED. We can support your regulatory needs in product certification. View our webpage or download our brochure to find out more.

Download the brochure

Visit our webpage

Listen back now

Medical Device Regulation – Impact on Manufacturer's Resources – 26th July 2016

Agreement has now been reached on the Medical Device Regulation (MDR), and the medical device industry will now need to understand the implication of the changes required in this long-awaited text. It is vital that manufacturers understand the impact on their business, and begin planning the necessary changes.

Listen back to Suzie Halliday, Head of the Notified Body, and Jay Katta, Certification Lead and Product Expert, to understand the implications of the new Regulation on your resources.

Listen back now

Can't attend?
Still sign up – we will make the recording and full slide deck available to you after the webinar.

BSI Medical Devices LinkedIn

Join the BSI LinkedIn Group to stay informed and updated with the latest news.

Visit the BSI Shop

Visit the BSI Shop to purchase the latest copies of standards and related guidance relevant to your product.

Keep up to date with transitions

With so many changes to the regulatory landscape, it's important that you stay up to date with developments. We have prepared dedicated web pages for the MDR, IVDR and ISO 13485:2016 – bookmark these pages and stay informed.

MDR Transition page

IVDR Transition page

ISO 13485:2016 Transition page