bsi. | Medical Devices

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Medical Devices complying with the Radio Equipment Directive.

The Radio Equipment Directive (RED), 2014/53/EU is a new Directive that will replace the long established Radio and Telecommunications Terminal Equipment Directive (R&TTE Directive), 1999/5/EC.

Published in the Official Journal of the European Union (OJEU) in March 2014, the RED is in a 2 year transition period and comes into force on 13th June 2016. The Directive is written in the new Legislative Framework and will bring significant changes for Medical Device manufacturers.

BSI are working towards designation under RED to be a Notified Body under Annex IV, Full Quality Assurance.

For products within the scope of the R&TTE Directive and that will remain within the scope of the RED:

- Products placed on the market before 13 June 2016 must use the R&TTE Directive.
- Products placed on the market between 13 June 2016 and 12 June 2017 can use either the R&TTE Directive or the RED.
- Products placed on the market after 12 June 2017 must use the RED

Read further detailed information about the Radio Equipment Directive.

Global market access with a global regulator.

New Medical Device and In-Vitro Diagnostic Revision support material.

Keep up to date with all the anticipated changes to the Directives with the two new webpages containing all the support material in one place.

IVDR revision page
MDR revision page

The revision pages will be updated frequently over the next few months so please ensure you bookmark the page to check for the latest content.

Complementary webinars on the regulatory changes in Europe.

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Case Study

BSI global teams have experience with many regulatory requirements for different global markets, allowing us to provide robust technical and regulatory expertise to support you in global market access.

Read more about why international manufacturers choose BSI

ISO 13485:2016 Transition

Training

ISO 13485:2016 Transition

The transition course introduces you to the new requirements and explores the changes between ISO 13485:2003/ EN 13485:2012 and the latest standard.

You'll be able to identify the gaps in your current Quality Management System (QMS) and start planning your transition and certification to comply with ISO 13485:2016.

ISO 13485:2016 Auditor Refresher

Are you an existing auditor with knowledge of ISO 13485 wishing to update your audit programme in line with ISO 13485:2016?

This course will refresh your auditing techniques and help you prepare to audit against requirements.

Find out more about the transition on our transition webpage

Missed the ISO 13485:2016 Webinars?

Publication of the Medical Device International Standard, ISO 13485

Update on the Proposed EU Medical Device Regulation. Paul Brooks.

Raise your awareness of the current state of the proposed EU Medical Devices Regulation (MDR) by hearing chapter by chapter what's likely to be in the MDR and how this will likely impact manufacturers.

The Future of Standards in Europe - harmonization and other recognitions of standards. Paul Sim.

A harmonized standard is a European standard developed by a recognized European Standards Organization: CEN, CENELEC or ETSI, created following a request from the European Commission. Manufacturers, economic operators or conformity assessment bodies use harmonized standards to demonstrate that products, services or processes comply with EU legislation.
New to the MDR is the instrument of Common Specifications (CS). This webinar will discuss how the introduction of CS sits with harmonized standards and how organizations can utilize both to maximum effect.

New Versions of ISO 13485 AND ISO 9001, what do you need to consider.

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