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# June Medical Device Newsletter, 2016

## Medical Devices: agreement reached on new EU rules

On 25 May 2016, new rules were agreed on medical devices and in vitro diagnostic medical devices.

Under the Dutch presidency, the European Council and representatives of the European Parliament reached a political agreement. This agreement is subject to the approval by the Council's Permanent Representatives Committee and of the Parliament's ENVI Committee.

The agreed two draft regulations are expected to achieve a twofold aim: making sure that medical devices and in vitro diagnostic medical devices are safe while allowing patients to benefit of innovative health care solutions in a timely manner.

Medical devices and in vitro diagnostic medical devices cover a wide range of products, from sticking plasters to hip replacements, and from pregnancy tests to HIV tests.

"This agreement matters to all citizens: sooner or later all of us enter into contact with medical devices to diagnose, prevent, treat or alleviate diseases. The deal reached will improve patients' health and it will help to enhance the quality of life of disabled persons. It will also ensure a level playing field for the 25,000 medical devices manufacturers in the EU, many of which are SMEs and which employ more than half a million persons", said Edith Schippers, Minister of Health of the Netherlands and President of the Council.

**Read the full article**

## Remain up-to-date with the MDR and IVDR revision

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

## Update on the Proposed MDR - Webinar

Update on the Proposed EU Medical Device Regulation. Paul Brooks.
Listen Back to the proposed EU Medical Devices (MDR) webinar, presented by Paul Brooks. Raise your awareness of the current state of the proposed EU Medical Devices Regulation by hearing chapter-by-

### Join BSI on LinkedIn

Join us on LinkedIn to share your knowledge, challenges and news.

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### Events and conferences

We run a variety of events and conferences from seminars, exhibitions and roadshows.

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# The DuPont™ Tyvek® Medical Packaging Transition Project

In June 2011, DuPont announced that it is changing the manufacturing lines of Tyvek® 1073B and Tyvek® 1059B to use newer technology, in order to ensure consistent and flexible supply.

**Background information**

DuPont has been working with a number of European Notified Bodies from the start of this project, including BSI. After review of the transition plans, BSI published a positioning statement to ensure that medical device manufacturers impacted by this change understood the requirements for CE Marked devices.

The statement details requirements for manufacturers who hold Annex II.4 or Annex III CE Certificates to submit a change notification for review by their Notified Body.

With regard to Annex II.3, Annex V or Annex VI CE Certificates, the Tyvek® change is not considered a significant change, and does not need to be reviewed prior to implementation.

**Click for more information**

# ISO 13485:2016 - Update

The latest edition of ISO 13485, the internationally recognised quality management system standard for the medical device industry, with over 27,000 certificates globally, is now published.

chapter discussion of what's likely to be in the final MDR text, and how this will likely impact manufacturers.

**Listen back now**

## BSI White Paper


"How to best prepare for and implement the up and coming MDR—do's and don'ts" discusses the MDR, outlining the changes that will impact manufacturers.

Download your copy now

## Updated ISO 13485 Training

BSI has a suite of courses to improve your understanding of the ISO 13485 standard. These courses, including our

To find out more about how BSI can support your transition journey from ISO 13485:2003 and the associated European Standard EN ISO 13485: 2012, visit our dedicated transition website.

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Expert Commentary on ISO 13485:2016

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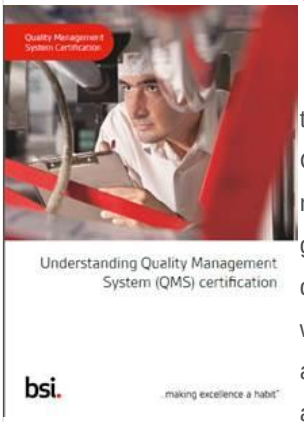
## BSI's approach to excellence




BSI selects and recruits professionals to conduct ISO 13485 audits. Candidates must have design or manufacturing or process knowledge and general knowledge on use of medical devices. Our assessment staff come to BSI with exceptional real industry experience and then go through rigorous internal training and BSI qualification processes including best practice quality systems auditing techniques, understanding critical manufacturing processes, interpretation of regulatory compliance expectations. BSI auditors are experts in current state-of-the-art requirements and are constantly trained on new requirements and future changes, BSI is always looking forward and ensuring our customers are prepared and well placed for future regulatory and compliance concerns.

> Visit our website to find out more

clauses-by-clause course for those new to the standard, and auditing courses for those participating in internal audits, have been updated to reflect the changes in ISO 13485:2016.
Click here to find out more about the courses we offer.

ISO 13485:2016 Transition

This comprehensive 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