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Medical
Devices

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March Medical Device Newsletter, 2017



Final Draft Text of IVDR and MDR now published. Have you started your transition planning?

The Medical Devices Directives are changing. Soon, the Medical Devices Directive (90/43/EEC) and the Active Implantable Medical Devices Directive (90/385/EEC) will be replaced by the Medical Devices Regulation, and the In Vitro Diagnostic Devices Directive (98/79/EC) by the In Vitro Diagnostic Devices Regulation.

When are the Medical Device Directives changing?

The Council has planned to approve the agreement at Ministers' level in September 2016. Following their legal-linguistic review, the draft Regulation will be then adopted by the Parliament and the Council, expected in May or June 2017.

The new rules will apply 3 years after publication for medical devices and after 5 years for IVD devices.

ISO 13485:2016, one year on. Are you ready?

The latest version of the Medical Device Quality Management System Standard, ISO 13485:2016, was published in February 2016. **We're now one year into the three year transition period; are you ready?**

You can learn more about the changes and plan your transition using our wealth of resources: [download our transition toolkit](#) or [visit our transition webpage](#) to learn more.

Talk to us about transitioning now?

[Speak to our team](#) about your plans, or contact us about [transferring to BSI](#).

bsigroup.com/IVDR-revision
bsigroup.com/MDR-revision

Use our Frequently Asked Questions documents as you prepare for your transition. Be sure that you understand what's changing and the timelines for implementation. Download your copy now:

[MDR FAQ](#)
[IVDR FAQ](#)

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Sign up to our complimentary webinar



Don't miss our Head of Notified Body, Suzie Halliday, as she discusses the Roles and Responsibilities under the new Medical Device and IVD Regulations. Listen live, or sign up to receive the recording and listen at your convenience:

[Roles and responsibilities in the Medical Device and IVD Regulations – 15 March 2017, 4pm GMT](#)

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