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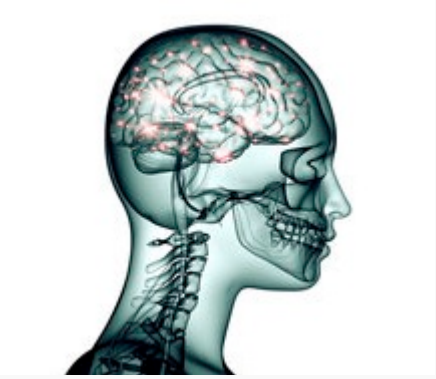


Regulatory review

Your monthly medical device update

November 2017

Start your preparation for the new MDR

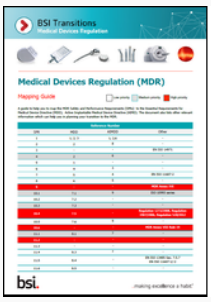
Use our new tools to assess your readiness to the MDR. Identifying the key changes will help you to understand the impact on your organization and where you need to start with your transition.

BSI MDR Readiness Review

The three year Medical Devices Regulation transition period is underway. Effective planning for your transition is essential to ensure you utilize the time effectively and have the necessary resources to meet your timelines.

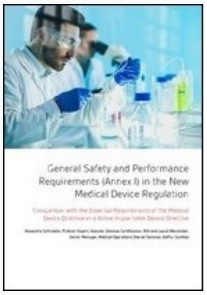
Use our interactive tool to complete a gap analysis of your current documentation and systems against the requirements of the MDR.

BSI MDR Safety and Performance Requirements Mapping Guide



Compare the Safety and Performance Requirements (SPRs) of the Medical Devices Regulation to the Essential Requirements of the Medical Devices Directive (MDD) and the Active Implantable Medical Devices Directive (AIMDD), and decide on your priorities for your transition.

BSI white paper: General Safety and Performance Requirements (Annex I) in the New Medical Device Regulation

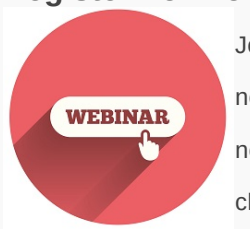


Our comprehensive white paper discusses the Essential Requirements of the MDD and AIMDD in comparison with the SPRs of the new Medical Devices Regulation, and includes a commentary on the key areas of change. Use this document as part of your preparation for the upcoming MDR, to ensure you're aware of the differences between the legislation.

Download now

Note: We will provide an equivalent set of documents for IVD products shortly. Find our IVDR resources on our dedicated webpage: **bsigroup.com/IVDRRevision**

Register now for our upcoming webinar



Join BSI experts **Alexandra Schroeder**, **Maritza Carballo** and **Ronald Rakos** for our new webinar on 29 November at 4pm GMT to understand the main impacts from the new SPRs and consider what actions you need to take now to be prepared for the change in requirements.

NEW BSI white paper - Do you know the requirements and your responsibilities for medical device vigilance reporting?

Our new white paper provides a detailed comparison of the vigilance requirements of the MDSAP Regulatory Authorities and the EU MDR, so you can understand more about the requirements you need to meet.

Download now

Upcoming webinar with BSI Global MDSAP Manager

This webinar will be presented on 16 November at 4pm GMT by **Patricia Murphy**, Global MDSAP Manager at BSI, and will provide a summary of the Program, focusing on timeline and actions you need to take to ensure continuity of supply.

Register now

BSI General Devices team: Breadth and depth of expertise

Our General Devices team has diverse expertise, from contact lenses to wound care, from device-drug combination products to devices utilizing animal tissue. Working with BSI gives you direct access to dedicated experts with specialist subject knowledge. Find our more about our team today.

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