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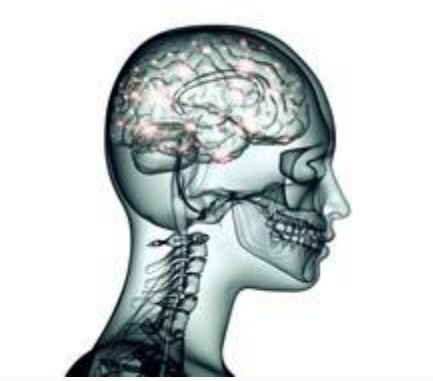


Regulatory review

Your monthly medical device update

September 2017

We're halfway through, don't jeopardize your certification

We're halfway through the ISO 13485:2016 transition period. Many manufacturers are yet to complete their transition, but the majority are much closer to meeting the new requirements than they think. Check your readiness and prepare for your upcoming transition assessment.

Check your readiness

MDR Safety and Performance Requirements white paper

The Safety and Performance Requirements (SPRs) of the

Medical Devices Regulation (MDR) replace the previous Directives' Essential Requirements (ERs) and outline the key areas to address within the Technical Documentation. Our new complimentary white paper provides comparison of the SPRs and ERs, allowing you to understand what's changing in more detail.

Download now

NEW complimentary BSI webinars

Usability factors, a new focus: do you know the requirements?

Don't forget to register for our new webinar on usability with BSI Product Expert, Richard Stein, 12 October at 4pm UK BST. This webinar will discuss relevant legislation and guidance relating to usability, allowing you to plan and launch your product effectively.

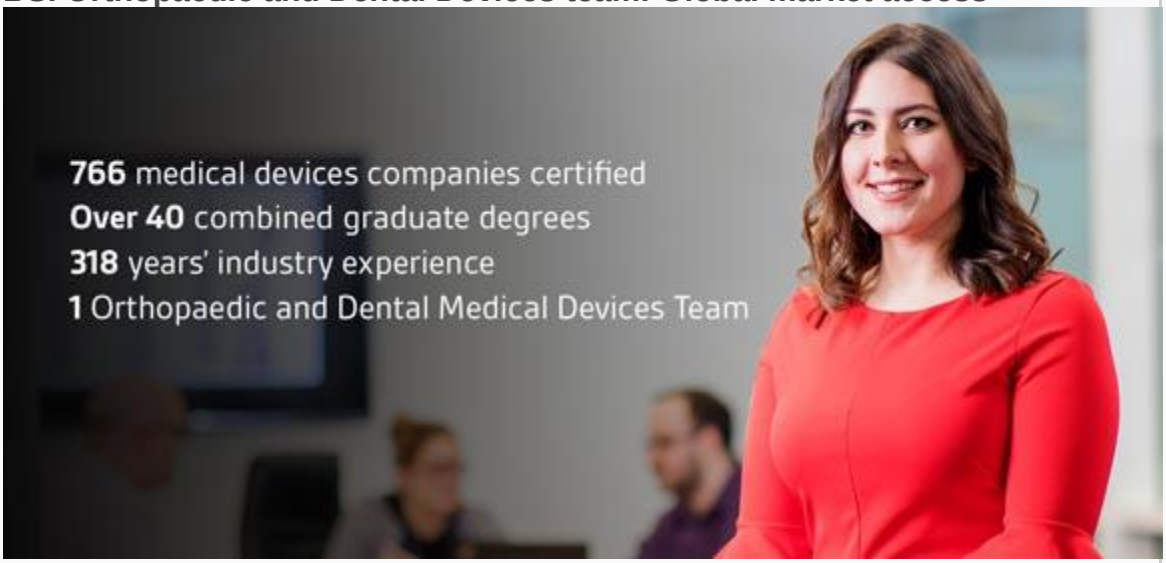
Sign up now

Technical Documentation requirements under the MDR, including requirements for your legacy files.

The new Medical Devices Regulation contains enhanced requirements for Technical Documentation, meaning that the information must be presented in a clear, organized, readily searchable and unequivocal way. This webinar, led by Dr Amie Smirthwaite, will help you consider what actions you need to take now to be prepared for the changing requirements. Join us on 30 October at 4pm UK GMT to find out more.

Sign up now

BSI Orthopaedic and Dental Devices team: Global market access



Our experts have the knowledge and expertise to provide you with robust certification services that will stand up to scrutiny. Work with specialists such as Dr Natasha Galley, a metallurgist with experience of magnesium alloys. Find out more about our expert Orthopaedic and Dental Devices team.

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