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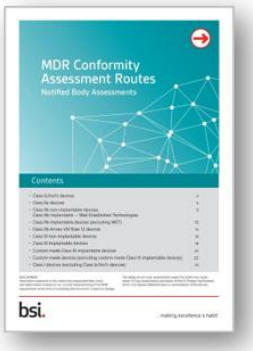
Regulatory review

Your monthly medical device update
July 2019

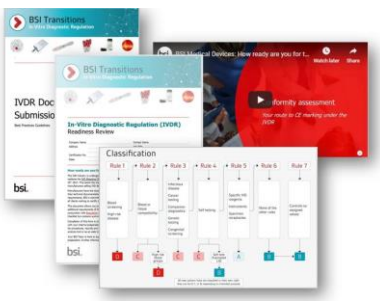
New MDR Conformity Assessment Routes guide



Are you looking for guidance on the new conformity assessment routes set out by the Medical Device Regulation (MDR)? Our new 'MDR Conformity Assessment Routes' guide provides a clear outline of the routes to conformity available for the various device classifications, and will be helpful to manufacturers looking to CE Mark their medical devices against the new Regulation. We'll also be hosting a webinar on this topic in July – register in the webinar section below.

Download now

Resources to support your IVDR transition



BSI is committed to ensuring a smooth transition for all clients wishing to certify to the In Vitro Diagnostic Regulation (IVDR) and we've produced a number of resources to support you. Visit our IVDR Revision page to find an IVDR Readiness Review, Classification Chart, Best Practice Guide, IVDR Readiness webinar

and more.

IVDR resources

MDR transition resources

With less than a year to go until full application of the MDR, we want to make sure our customers have the resources they need to transition smoothly and on time. Visit our MDR Revision page for resources including white papers, MDR Readiness Review, Mapping Guide and Best Practice Submissions Guidelines to support your transition arrangements. You can also watch a recording of Dr Jayanth Katta, Regulatory Lead for the BSI UK Notified Body, speaking at MedTech Summit 2019 in Brussels.

MDR resources

Register for upcoming webinars

Hear our experts talk about the latest in Regulatory Affairs and Standards.

MDR Conformity Assessment Routes – Dr Jayanth Katta

Tuesday 16 July

Join this webinar where Dr Jayanth Katta, Regulatory Lead for the BSI UK Notified Body, will introduce our new Conformity Assessment Routes material, which will be a useful resource to manufacturers looking to CE Mark devices under the Medical Device Regulation.

Register now

ISO 14971:2019 Risk Management for Medical Devices – Dr Peter Bowness

Wednesday 18 September

In the medical device industry, risk management is a vital part of all your company's processes. Hear from Dr Peter Bowness, Medicinal and Biologics Technical Team Manager and member of the UK technical committee for risk management in medical devices, about the updated ISO 14971 and what has changed from the previous version of the standard.

Register now

Interested in Advanced Access ISO 14971? Visit the BSI Shop.

150 Full Text ASTM Medical Device Standards now added to Compliance Navigator

We are pleased to announce the recent addition of 150 full text ASTM medical device standards to Compliance Navigator to support our subscribers' compliance processes for US requirements.

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For all general inquiries, call 1-888-429-6178 or visit our website

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