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Regulatory review

Your monthly medical device update
May 2020

Guidance on the Medical Device Regulation (MDR)

Watch our series of videos to hear Dr Suzie Halliday, BSI Regulatory Director and Head of the UK Notified Body, provide guidance on the MDR:

- Post-Brexit and second corrigendum
- European Commission rolling plan
- EUDAMED and UDI assignment

Please note these videos were recorded in the UK before the COVID-19 social distancing restrictions came into force.

Do you manufacture drug-device combination products?

Join our webinar on **Wednesday 1 July 2020** to hear from Dr Jennifer Durrant, Global Head of Medicinal and Biologics and Dr Jonathan Sutch, Medicinal Technical Specialist about BSI's perspective on Article 117 and drug-device combination products.


Choose from one of two sessions:

1 July, 09:00 BST – Register now

1 July, 16:00 BST – Register now

Find out more about drug-device combination products and Article 117, including an article by Dr Jonathan Sutch that recently featured in the Journal of Medical Device Regulation.

Visit website

Resources to support your transition to the MDR

We've produced a number of resources for you to use to support your transition to the MDR:

- Listen back to our recent webinar, MDR – what we currently know with Dr Suzie Halliday and Dr Jayanth Katta.
- Download our MDR Conformity Assessment Routes guide for an outline of the various routes to conformity with the MDR.

MDR resources

In Vitro Diagnostic Regulation (IVDR) application process

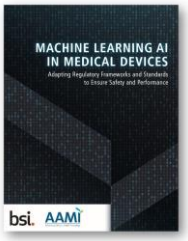
Friday 17 June 2020, 16:00 BST


Want to know more about the IVDR application process? Join our webinar to hear guidance from Todd Moorman on how to prepare a successful IVDR application to BSI for notified body services. He will be joined by Dr Erica Conway for a Q&A session.

Register now

Machine learning AI in medical devices | Joint BSI and AAMI whitepaper

Our recent whitepaper examines how AI is different from traditional medical devices and medical software; explores the implications of those differences; and discusses the controls necessary to ensure AI in healthcare is safe and effective.



Download white paper

Latest MDR guidance: vital clinical evidence documents, 28 April

The European Commission guidance documents on compliance with the MDR, published in April and May 2020, include six documents focused on clinical evidence:

- Guidance on safety reporting in clinical investigations / Appendix: Clinical investigation summary safety report form
- Guidance on PMCF evaluation report template
- Guidance on PMCF plan template
- Guidance on sufficient clinical evidence for legacy devices
- Guidance on clinical evaluation – Equivalence
- Summary of safety and clinical performance

More EC guidance

Save 15% on virtual training with Connected Learning Live

Due to the current COVID-19 pandemic, we are delivering all scheduled courses until 28 August via online delivery using our highly-interactive virtual classroom - Connected Learning Live, so delegates can continue their learning in the comfort of their own environment.

Experience Connected Learning Live with our complimentary taster session on Thursday 4 June covering ISO 13485:2016.

Book ISO 13485 taster session

Have a course in mind?

Use the code CLL2020 to receive a 15% discount on these courses when booking online. Terms and conditions apply. See the website for details.

Course Dates

2 June | ISO 13485:2016 Introduction

3-4 June | ISO 13485:2016 Internal Auditor

15 June | Technical Documentation for In Vitro Diagnostic Devices (IVDs)

15-19 June | ISO 13485:2016 Lead Auditor

22-23 June | ISO 13485:2016 Implementation

22 June | CE Marking Medical Devices with Software

24-25 June | ISO 13485:2016 Clause by Clause

29 June | ISO 14971:2019 Risk Management for Medical Devices: Requirements

View all courses

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