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Regulatory review

Your monthly medical device update
June 2021

Featured in this Newsletter

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UKCA - new website and FAQs

Download our UKCA webinar FAQs to know more about taking devices to market in Great Britain post-Brexit.

More information on UKCA can be found on our [website](#)

[Download the FAQ](#)



IVDR Company Information Form (CIF) - Device Schedule

We have developed a presentation to guide you through completing the 'Device Schedule' section of the Company Information Form (CIF) when applying for conformity assessment under the IVDR.

The Device Schedule provides BSI with the information we need to fully understand the scope of your application and the information to be included on the certificate of conformity; it also ensures that we, as a Notified Body, are complying with the Regulation. A comprehensive Device Schedule enables us to complete the quotation process more efficiently, reducing the probability that the scope of the application will need to be changed at a later date.

For more information about how BSI can support your transition to the IVDR, please visit our [dedicated IVD team webpage](#).

[Download the Device Schedule tutorial](#)

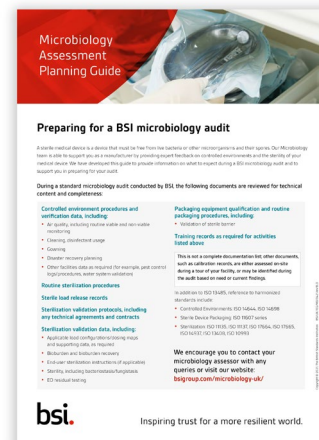
Microbiology Assessment Planning Guide

We have developed this guide to provide information on what to expect during a BSI microbiology audit and to support you in preparing for your audit.

Learn about our Microbiology team and the broad range of medical, pharmaceutical, industry and regulatory experience, including product design and development, manufacturing, sterilization and product testing.

Further information about microbiology can be found on our [website](#).

[Download the planning guide](#)



Listen back to our most recent Webinars

IVDR Lessons Learnt Webinar

Listen back to The IVDR Lessons Learnt webinar which was an exclusive extended 3-hour webinar.

This was presented by Dr Erica Conway, BSI's Global Head of IVD Medical Devices, along with subject matter experts, Dr Liz Harrison, Dr Heike Möhlig-Zuttermeister and Judith Prevoo.



[View the On Demand recording](#)

MDR Lessons Learnt Webinar

Listen back to our recent webinar on MDR Lessons Learnt with Kevin Madden, Team Training Lead and Technical Team Manager in the Orthopaedic and Dental technical team. Kevin looked at the critical lessons we have learnt and how you can use these to improve your submissions to BSI. Kevin was joined by Chris Wylie, Global Head, Orthopaedic & Dental Devices, BSI for the Q&A session.



[View the On Demand recording](#)

Listen back to our MDR webinar series in German language

Virtuelles MDR Expertenfrühstück

From April to June we hosted three webinars in German language about Technical Documentation, Clinical Evaluation and Post Market Surveillance under the MDR, presented by our three German speaking experts Anna Mirabelli, Hans-Gerd Evering and Thomas Dörge. Find all event details [here](#).

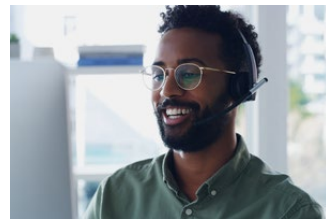


Listen back to this webinar series in German language.

[View the On Demand recordings](#)

Upcoming trainings for your calendar

Use the summer break to refresh your knowledge. Here you will find a selection of upcoming training courses:



Requirements of the IVDR, 9 July 2021 - [Book now](#)

Performance evaluation and clinical evidence for IVDs, 15 July 2021 - [Book now](#)

IVDD to IVDR transition course, 02 August 2021 - [Book now](#)

[View all training courses](#)

Remote access to regulatory documents made easy | Compliance Navigator free trial



Whilst working with medical device standards is challenging and time-consuming in and of itself, working remotely adds an extra layer of complexity into the mix. With a subscription to Compliance Navigator, you can access your regulatory documents and standards easily wherever you're working

from. All you need is an internet connection and you're set. What's more, we're offering you a free trial so that you can see the benefits of Compliance Navigator for yourself.

[Claim your free trial](#)

Events for your calendar

Find out the latest information about BSI Medical Devices [Events and Conferences](#).



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