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Regulatory review

Your monthly medical device update
June 2021

Featured in this Newsletter

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

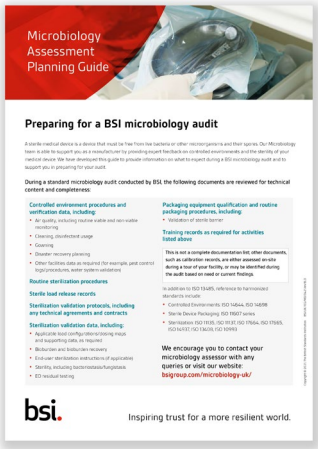
We have developed a presentation to guide you through completing the 'Device Schedule' section of the Company Information Form (CIF) when applying for conformity assessment under the IVDR.
The Device Schedule provides BSI with the information we need to fully understand the scope of your application 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

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