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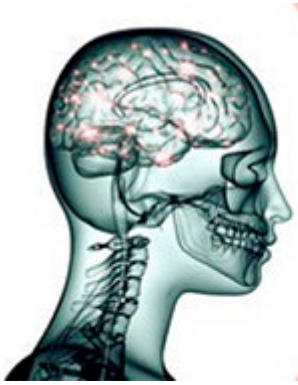


Regulatory review

Your monthly medical device update

March 2023

Featured in this Newsletter

First IVDR Annex IX Chapter II Class D Certificate issued

BSI IVDR Notified Body issued its first IVDR Annex IX Chapter II Class D certificate on 11 January 2023. The manufacturer was Roche Molecular Systems and the certified device is used to screen blood donations for HEV infection.

Alex Laan, Head of BSI IVD Notified Body, commented: "Understanding the challenging regulatory circumstances for conformity assessment of Class D IVDs in Europe, without the availability of European Reference Labs, it gives us pride to see that our IVD Team was able to come to a positive conclusion to support the first IVDR certification for the HEV assay of Roche. This is also going to be a very positive signal towards blood transfusion centres that use the device for screening blood donations on HEV infections, supporting the EU healthcare system."

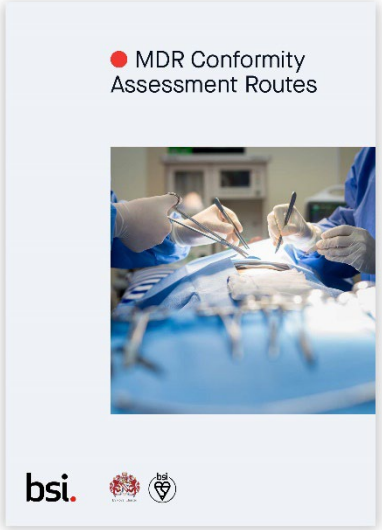
Liz Harrison, BSI Global Head of IVD, commented: "This is a huge milestone that we have been working towards since our BSI Netherlands IVDR designation in December 2019. I would like to thank our team of technical reviewers and QMS assessors for their diligence in ensuring high risk devices undergo rigorous assessment. I also want to thank our customers for working with us over the challenging IVDR transition. In the absence of designated European Reference Laboratories, BSI has implemented a risk-based approach to the certification of Class D devices and we are pleased to issue our first certificate in 2023."

We're here to support you

Our guiding brochure will support you in understanding conformity assessment routes and in selecting the most suitable for your in-vitro diagnostic device. Click **here** to download our latest brochure.

Download brochure

Open for applications for Class Im, Ir and Is medical devices



Are you looking for a Notified Body to certify your Class I device? BSI is a leading Notified Body with full-scope designation under the MDR.

We are open for applications **for Class Im, Ir and Is** medical devices!

Talk to BSI today and start your journey!

Take the opportunity to navigate our new guide on MDR Conformity Assessment Routes.

Clinical Masterclass on demand - Preparing a Post Market Clinical Follow Up & Evaluation Report

Our clinical masterclass series of webinars for 2023 have now come to an end.

These 5 webinars looked at various aspects of the MDR, from preparing a Clinical Evaluation Plan, to supporting you with preparing a Clinical Evaluation Report, as part of an in-depth, 2- part webinar. Additionally, we also provided guidance on preparing a Post Market Clinical Follow Up Plan and Evaluation Report (PMCF) as well as helping you to understand how best to produce a compliant Summary of Safety and Clinical Performance (SSCP) for both healthcare professionals and patients.

To find out more and to watch all 5 webinars on demand, click on the button below.

Watch the Clinical Masterclass Series On demand

New Webinar - Understanding Periodic Safety Update Reports and how to submit your PSUR

Join us on 21 March for our Medical Devices webinar on 'Understanding Periodic Safety Update Reports and how to submit your PSUR'.

This webinar will provide manufacturers with an understanding of BSI's expectations in relation to PSURs and provide an overview of the recent guidance related to PSURs (MDCG 2022-21).

Manufacturers will learn how and when to submit PSURs to BSI using the BSI Electronic Client Portal and also when they are required to update and provide SSCPs alongside the PSUR.

Participants will gain:

- An understanding of BSI expectations in related to PSUR
- An overview of MDCG 2022-21
- How to correctly submit PSURs to the notified body
- When to submit SSCPs alongside PSURs

Register for the PSUR webinar

Medical Devices Training Courses

We understand the challenges of meeting regulatory requirements and maintaining quality management systems and have a diverse range of training courses available to you.

We're also one of the few certification bodies offering diverse medical device training portfolios consisting of specialized training classes.

To find out more on our training offering, please **click here**.

The Digital Revolution in Regulatory Document Management| BSI Compliance Navigator

Manage your risk and save time with BSI Compliance Navigator. From discovering applicable requirements to anticipating changes to standards and performing gap analyses, BSI's Compliance Navigator is with you every step of the way.

Start your free trial

Events for your calendar

We have some fantastic events for 2023. Take a look now at our calendar of events for 2023.

Don't miss the opportunity to interact with BSI experts or connect with our commercial team to discuss your certification requirements. Find out more about our latest Events and Conferences.

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