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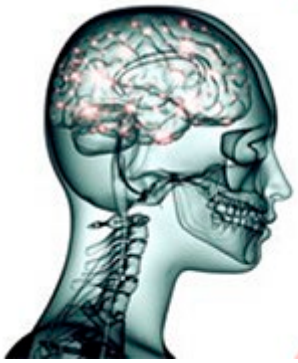


Regulatory review

Your monthly medical device update

February 2023

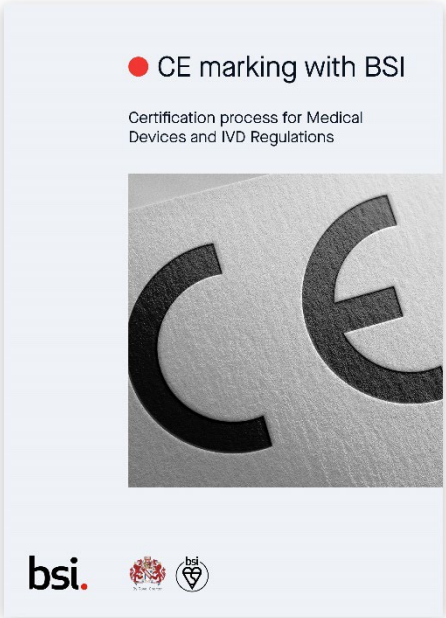
Featured in this Newsletter

CE marking with BSI

Visit our **CE dedicated webpage** to discover our **new brochure** on CE marking with BSI!

This guide will take you through our certification process starting from your application to BSI to your CE Certificate issue.

Discover the process and the information needed to certify your device with BSI.



Clinical Masterclass on demand - Preparing for a Clinical Evaluation Report (part I and II)

Due to popular demand, our clinical masterclass series of webinars is here again for 2023 with new and exciting content for you.

These 5 webinars will help you focus on 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'll also provide 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.

Listen back to our second and third webinars of the series:

Preparing a Clinical Evaluation Report (Part I)

Preparing a Clinical Evaluation Report (Part II)

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

Register for the Clinical Masterclass Series

MDR Mapping Guide now available

Visit our MDR dedicated webpage to discover our new MDR Mapping Guide!

This guide will help you to map the MDR General Safety and Performance Requirements (GSPR) to the Essential Requirements for the Medical Device Directive (MDD), and Active Implantable Medical Device Directive (AIMDD).

Other relevant information which can help you in planning your transition to the MDR is also available.

Download Mapping Guide

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

Join us 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 2022-25
- How to correctly submit PSURs to the notified body.
- When to submit SSCPs alongside PSURs

Register for the PSUR webinar

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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