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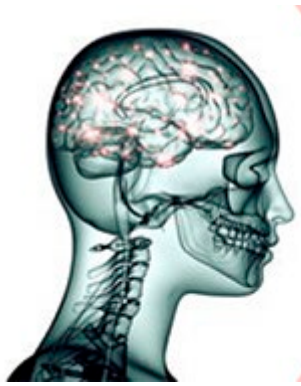

# Regulatory review

## Your monthly medical device update
## November 2021

## Featured in this Newsletter



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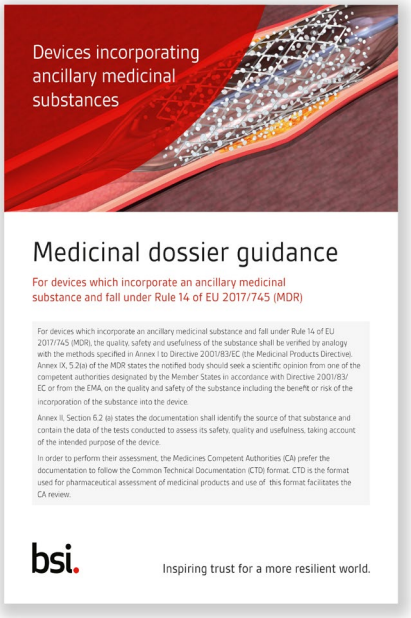
## New BSI medicinal dossier guidance

For devices which incorporate an ancillary medicinal substance and fall under Rule 14 of EU 2017/745 (MDR), the quality, safety and usefulness of the substance shall be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC (the Medicinal Products Directive). Annex IX, 5.2(a) of the MDR states the notified body should seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or from the EMA, on the quality and safety of the substance including the benefit or risk of the incorporation of the substance into the device.




Download our guidance for devices which incorporate an ancillary medicinal substance and fall under Rule 14 of EU 2017/745 (MDR).

Find out more on our website.

Download our guidance

## EU regulatory update

### New Eudamed modules now available

The EUDAMED module on UDI/device registration and the module on Notified Bodies and Certificates are open, so economic operators and notified bodies can start entering data in EUDAMED on a voluntary basis.
As a Notified Body, BSI is heavily involved in the testing of EUDAMED and has provided a significant amount of feedback to the EUDAMED developer team. We will confirm when BSI will start using EUDAMED. In parallel, we are working to ensure our internal processes are updated to interact with EUDAMED seamlessly.

### MDCG issues guidance on the classification of medical devices

The Medical Device Coordination Group (MDCG) has issued MDCG 2021-24, a set of guidelines on the classification of medical devices, with information on the purpose and practical relevance of classification and how to apply the classification rules.

Read the MDCG 2021-24 document

Stay in touch with future MDCG guidance

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## Upcoming Webinar - AIMDD to MDR transition - what you need to know

Join this insightful webinar to hear from Thomas Doerge, BSI's Global Head of Active Implantable Medical Devices, talk about MDR lessons learnt so far for AIMD products, as well as tips on making applications and the Technical Documentation requirements under the MDR.
In this webinar, Thomas Doerge will be joined by subject matter experts Concetta Gallo and Jazzmyne Buckels.

Choose from one of two sessions on **Tuesday 23 November 2021**:

Tuesday 23 November: 09.00 – 10.00 GMT **Register now**
Tuesday 23 November: 16:00 – 17:00 GMT **Register now**

Download the AIMD brochure

Listen back to our recent interview with Dr Thomas Doerge answering key questions related to CE marking for Active Implantable Medical Devices under the MDR and the important elements to consider when submitting technical documentation for an MDR application.

The interview is developed in partnership with the Informa Connect MedTech Series.

Watch the interview here

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## Listen back to our most recent webinar: Personalised Medical Devices – what you need to know

The Personalised Medical Devices - what you need to know webinar, was presented by Judith Prevoo, Regulatory Lead and Tim Marriott, Principal Technical Specialist & Scheme Manager.

The webinar looked in detail at the regulatory requirements for personalised medical devices as well as an explanation of common pitfalls of classifying personalised devices.

View Recording

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## European amendment published for medical devices quality management system standard | Compliance Navigator Blog

An amendment to EN ISO 13485:2016 – Medical devices – Quality management systems – Requirements for regulatory purposes – was published in September 2021. The amendment replaces the European Foreword and Annexes ZA, ZB and ZC.

Read full blog post

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## Events for your calendar

Find out the latest information about BSI Medical Devices Events and Conferences.


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