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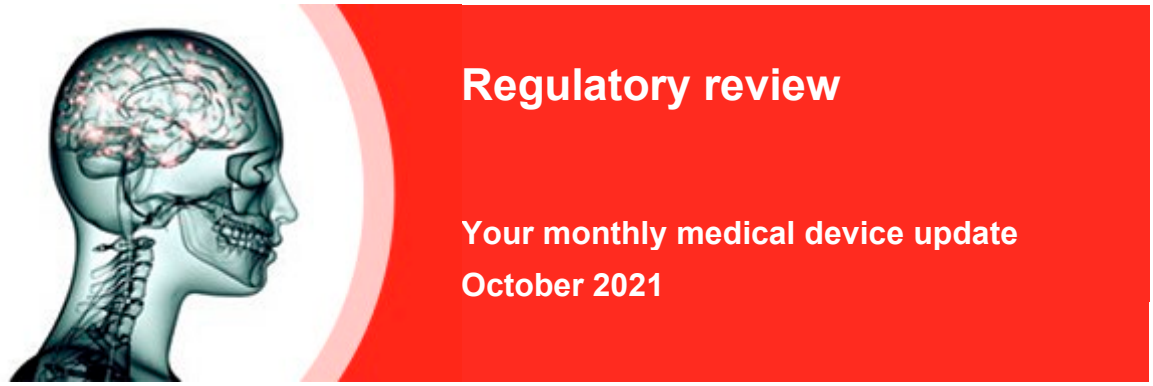


# Regulatory review

## Your monthly medical device update
## October 2021

## Featured in this Newsletter



## IVDR Classification

The In Vitro Diagnostic Regulation (IVDR) (EU) 2017/746 is the new EU legislation applicable to in vitro diagnostic (IVD) medical devices. Entering into force on the 25 May 2017 marking the start of a five-year transition period for manufacturers and economic operators, the IVDR replaces the EU In Vitro Diagnostics Directive (IVDD) 98/79/EC.

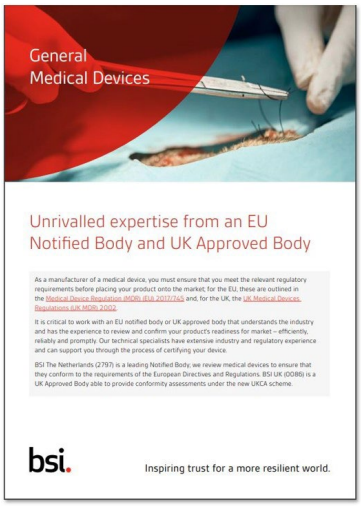
Manufacturers wishing to apply to a notified body for a conformity assessment of their IVD medical device have until the Date of Application of the IVDR in May 2022 to update their Technical Documentation to meet the requirements and comply with the new, more stringent Regulation.

All devices will need to be divided into classes. This classification map will allow you to allocate your device correctly under the IVDR.

Download the IVDR classification rules

## General Medical Devices Brochure

Our General team of highly trained technical specialists are product experts who work with device manufacturers and understand the specifics of complex medical devices.
The team has an average of 20 years' industry and regulatory experience, and we are able to provide conformity assessments under the EU MDR and UK MDR (2002).




Find out more on our website.

General Medical Devices Brochure

## Listen back to our most recent webinar - What you need to know about the Periodic Safety Update Report (PSUR) & Vigilance under the Medical Device Regulations

The what you need to know about the Periodic Safety Update Report (PSUR) & Vigilance under the Medical Device Regulation – conformity assessment process and documentation requirements for submissions webinar was presented by Richard Holborow, Head of Clinical Compliance, BSI.

The webinar looked in detail at the post market requirements as listed under Articles 86 and 87 of the MDR, as well as which information is required for the PSUR and which vigilance events are reportable.

If you missed the webinar or were not able to join you can view the recording and presentation slides

here.

## Upcoming Webinar - Personalised Medical Devices - what you need to know

Join Dr Tim Marriott, Senior Technical Specialist and Scheme Manager, BSI, to hear about important insights into routes to conformity for personalised medical devices. Tim will also be joined by Judith Prevoo, Regulatory Lead, BSI.

Participants will gain an understanding of the regulatory requirements for personalised medical devices as well as an explanation of common pitfalls of classifying personalised devices.
The webinar is open to everyone and is particularly suitable for those individuals who have an interest in the regulatory paths for personalised medical devices, as well as manufacturers of personalised medical devices.
Please join us for this insightful webinar and choose from one of two sessions:

Thursday 04 November: 10.00 – 11.00 CET **Register now**
Thursday 04 November: 17:00 – 18:00 CET **Register now**

## Digital pre-applications for CE marking, UKCA and QMS services


We are pleased to hear initial feedback for our new digital pre-applications portal for CE marking, UKCA and QMS services. The portal will allow you to access the pre-application process through a digital interface, and it replaces our Company Information Forms.

Feedback includes:

"Transparency and oversight of current and previous applications, more accurate CIF completion, saving time in the overall process and the flexibility to allow different users to update the information."

"Puts the Manufacturer in control of their applications."

"Visibility of the history of applications and overview of the status".

Complete the form

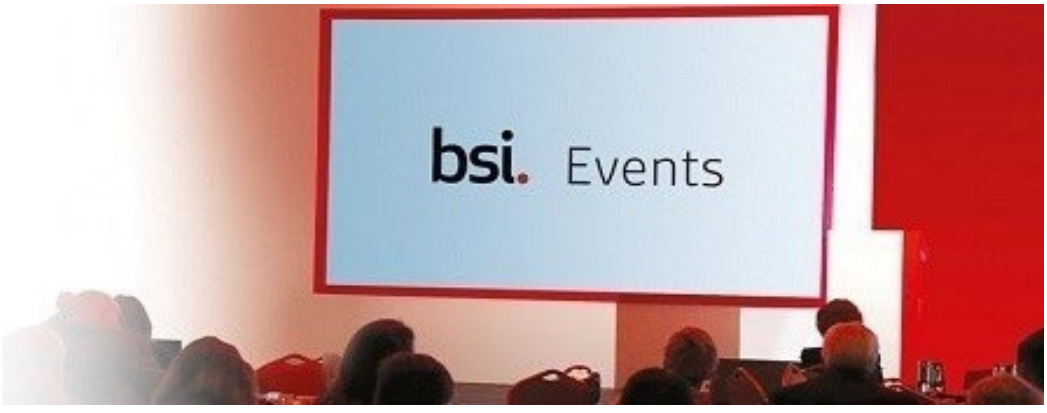
**Learn about key MDR SSCP requirements | New white paper published**

The Summary of Safety and Clinical Performance (SSCP) is a new requirement under the European Medical Devices Regulation 2017/745 (EU MDR), applicable to Class III and implantable devices. This white paper explains the purpose and contextual background of the SSCP and summarizes the key requirements and recommendations from the MDR and MDCG 2019-9 guidance.

Download whitepaper

## Events for your calendar

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



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