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# Regulatory review

**Your monthly medical device update**
**February 2020**

## Brexit update, successes of 2019 and the year ahead

"Back in June 2016, we made a pledge to our clients that we would provide seamless, uninterrupted access to the medical devices market, whatever the outcome of Brexit. We have delivered on that promise."


Hear Dr Manuela Gazzard, Group Director for BSI Regulatory Services, reflect on BSI's successes of 2019 and consider what's in store for 2020 as the new, more stringent MDR comes into force and countdown to the IVDR continues.

Watch video

Latest Brexit update

## Second corrigenda to the MDR and IVDR published

The EU Commission has now published the **second corrigendum to the MDR** and the **second corrigendum to the IVDR** in the Official Journal of the EU (OJEU).

The key change to the **MDR** states that devices classified as Class I under the MDD can continue to be placed on the market until the 26 May 2024 if the following conditions are met:

- The manufacturer has issued a 'Declaration of Conformity' under the MDD prior to 26 May 2020

- The devices require notified body involvement under the MDR
- There are no significant changes in the design or intended purpose of the devices after the 26 May 2020.

The key change to the **IVDR** affects devices that fall under Rule 2 of Annex VIII, which includes devices intended to be used for blood grouping or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion, transplantation or cell administration.

Read more

## BSI issues first Article 117 Notified Body Opinion

2019 was a year of firsts for BSI, and 2020 kicked off with another fantastic achievement as we became the first ever to issue a Notified Body Opinion to a manufacturer for a drug-device combination product under MDR Article 117. This is thanks to the team for working incredibly hard to provide this expertise to our clients.

Read more

## There's still time to book your place at our IVDR Spring 2020 Roadshow

The BSI EU In Vitro Diagnostic Regulation (IVDR) Roadshow will soon be returning to various locations across Europe and the USA.

Come along to hear the latest IVDR updates from BSI and engage face-to-face with the only organization with two Notified Bodies with full scope designation to the IVDR.

**Europe**

- London, UK – 3 March 2020
- Munich, Germany – 10 March 2020
- Amsterdam, Netherlands – 25 March 2020

Register interest

**USA**

- San Jose, USA – 16 March 2020
- San Diego, USA – 18 March 2020
- Boston, USA – 20 March 2020

Register to attend

## CLSI module coming soon to Compliance Navigator

We are delighted to announce that 71 Clinical and Laboratory Standards Institute (CLSI) standards are coming soon to Compliance Navigator as an optional add-on collection. The collection includes:

- M100 - Performance Standards for Antimicrobial Susceptibility Testing
- EP09 - Measurement Procedure Comparison and Bias Estimation Using Patient Samples
- MM17 - Validation and Verification of Multiplex Nucleic Acid Assays

Find out more

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