MD REGULATORY DIGEST

FOCUS ON

MEDICAL DEVICE REGULATION (EU) 2017/745

The new **Medical Device Regulation (MDR)**, adopted on 5 April 2017 and entered into force on 25 May 2017, brings about a period of great change, uncertainty and opportunity within the medical technology sector. The new rules will apply on **May 2020**, after a transitional period of 3 years. The MDR will replace the existing Directives.

This new regulation aims to establish a **modernized and more robust EU legislative framework** to ensure better protection of public health and patient safety, bringing higher traceability, transparency and homogeneity between European countries. To address this, the MDR contains a series of important improvements to modernize the current system. Among them are:

- The reinforcement of the criteria for **Notified Bodies**;
- The inclusion of non-medical devices (e.g. contact lenses) and **new classification rules** for medical devices;
- The reinforcement of the rules on clinical evidence and a new **pre-market scrutiny process**;
- The strengthening of **post-market surveillance** requirements;
- A new European database on medical devices (**EUDAMED**);
- The introduction of a Unique Device Identification System (**UDI**);
- More **coordination** between European countries.

BSI & BREXIT

The BSI UK (0086) has been notified by the MHRA to conduct conformity assessment audits under EU Regulation 2017/745 and became the first notified body designated under the MDR. However, without conclusive negotiations, a no-deal Brexit is approaching which will make all the CE certificates issued by the BSI UK obsolete. As of 30 March 2019, the UK will become a third country and the **CE certificates will lose their validity.**

The notified body strongly recommends manufacturers migrate their existing BSI UK NB (0086) CE certificates to BSI NL NB (2797) as a matter of urgency. Very importantly, once CE certificates lose their validity post 29 March, **they will not be able to be transferred or migrated to an EU notified body.** Products will lose market access, and a new conformity assessment will be required.