Risk management in accordance with the Medical Device Regulation

by Miriam Schuh

The situation at the outset

Since 25 May 2017, the new European regulations for medical devices and in vitro diagnostics (IVD) have been in force. After transitional periods of three and five years respectively, these two regulations (MDR and IVDR) will supersede the provisions of the European directives that still apply at the moment. The new regulations are, among other things, designed to guarantee a higher degree of safety for patients and users of medical devices. To achieve this objective, the obligations of manufacturers in particular have been extended and tightened considerably – throughout the entire life cycle of their products.

The new obligations of the manufacturers are covered extensively in Article 10 of the MDR. One remarkable thing is that following the central requirement in Article 10 1. of the MDR to manufacture medical devices and place them on the market in future in accordance with the requirements of the MDR (i.e. so as to be MDR-compliant), the requirement for risk management is now legally standardised for the first time in Article 10 2.

According to the specifications of the MDR, quality management systems will thus in future have to contain clear processes for risk management, the planning, implementation and assessment of which must be documented and verified. Systematised gathering of data and documentation are obligatory and also serve, above all, to keep the technical documentation up to date. At the same time, the requirements of EN ISO 13585: 2016 must be met and – just as with risk management – in addition, detailed processes created for the conducting of clinical assessments, and for market observation after the products have been launched.

Recommendation

The existing risk management systems in a company should be reviewed in detail to see how well they fit in with the specifications of the MDR, and if necessary adapted. Any non-compliance of the risk management system with the requirements of the new regulation is a breach of the organisational obligations of the manufacturer, and it can, if patients, users or other third parties are damaged, result in claims being made on principles of tort as well as under product liability regulations. Finally, a breach of the manufacturer's obligations as prescribed by Article 10 of the MDR can also constitute failure to comply with the MDR and, in the worst case, lead to product recalls being ordered by the authorities.

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