

EN
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Answer given by Mr Várhelyi
on behalf of the European Commission
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Regulation (EU) 2017/745 on medical devices¹ and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices² lay down general safety and performance requirements to ensure a high level of protection of health and safety of patients and users while supporting innovation. Such requirements are implemented via the corresponding conformity assessment procedures. Technical specifications in support of those requirements are usually laid down in harmonised standards. Devices designed and manufactured in compliance with harmonised standards benefit from a presumption of conformity with the corresponding requirements of the applicable legislation. However, those requirements are applicable in all Member States regardless of the existence of standards.

Harmonised standards are available on quality management systems³ and risk management⁴ for blood-glucose monitoring systems⁵ and for infusion pumps and controllers⁶, among others. Other harmonised standards are being developed or revised by the relevant European standardisation organisations, CEN and CENELEC⁷, upon a request from the Commission⁸. Where no harmonised standards exist, where relevant standards are not sufficient, or where there is a need to address public health concerns, the Commission may adopt common specifications in respect of the requirements set out in the abovementioned Regulations.

The responsibility on the quality, safety and effectiveness of medical devices on the EU market lies with the competent authorities of the Member States in charge of the enforcement of the EU rules on medical devices and the related market surveillance activities. The Commission ensures coordination at EU level through the Medical Device Coordination Group (MDCG).

¹ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1, ELI: <http://data.europa.eu/eli/reg/2017/745/oj>).

² Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176, ELI: <http://data.europa.eu/eli/reg/2017/746/oj>).

³ EN ISO 13485:2016 + AC:2008 + A11:2021 Medical devices - Quality management systems - Requirements for regulatory purposes.

⁴ EN ISO 14971:2019 + A11:2021 Medical devices - Application of risk management to medical devices.

⁵ EN ISO 15197:2015 *In vitro* diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.

⁶ IEC 60601-2-24 Medical electrical equipment - Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers.

⁷ The European Committee for Standardization (CEN) and the European Electrotechnical Committee for Standardization (CENELEC): <https://www.cenelec.eu/european-standardization/cen-and-cenelec/>.

⁸ Commission Implementing Decision of 14.4.2021 on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards medical devices in support of Regulation (EU) 2017/745 of the European Parliament and of the Council and *in vitro* diagnostic medical devices in support of Regulation (EU) 2017/746 of the European Parliament and of the Council (C(2021)2406 - Standardisation request M/575, as amended): https://ec.europa.eu/growth/tools-databases/enorm/mandate/575_en.