

EN

E-002033/2025

Answer given by Mr Várhelyi
on behalf of the European Commission
(18.8.2025)

The Commission recognises the strategic importance of the medical devices sector. Therefore, it is a priority to work on addressing challenges identified in the regulatory framework for medical devices and in vitro diagnostic medical devices. The Commission is conducting a targeted evaluation of the concerned regulations. In 2025, based on this targeted evaluation, the Commission will propose legislation that strikes a balance between simplifying EU regulations related to medical devices and in vitro diagnostics, with a view to facilitate businesses' operations across the EU single market and effectively protecting patient safety and public health¹.

The targeted evaluation is part of the Commission's ongoing work to streamline and improve the EU's rules for medical devices. On 25 June 2025, the Commission adopted an implementing regulation that simplifies the provisions of instructions for use of medical devices and further digitalises healthcare systems². On 7 July 2025, it adopted a decision to establish an expert panel to provide scientific and clinical advice concerning devices intended for small patient populations, such as children or patients with a rare disease³. Further measures are in preparation.

One of the tasks of the Medical Device Coordination Group (MDCG), set up by the Regulation on medical devices and composed of representatives of each Member State, is the development of guidance aimed at ensuring effective and harmonised implementation of the Regulations on medical devices and in vitro diagnostics⁴. The MDCG has produced more than 100 guidance documents that are available online⁵.

¹ See Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Choose Europe for life sciences: A strategy to position the EU as the world's most attractive place for life sciences by 2030, COM(2025)525 final, 2.7.2025.

² Commission Implementing Regulation (EU) 2025/1234 of 25 June 2025 amending Implementing Regulation (EU) 2021/2226 as regards the medical devices for which the instructions for use may be provided in electronic form, OJ L 26.6.2025, ELI: http://data.europa.eu/eli/reg_impl/2025/1234/oj.

³ https://eur-lex.europa.eu/eli/dec_impl/2025/1324/oj/eng.

⁴ See Article 105, point (c), of Regulation (EU) 2017/745 on medical devices, OJ L 117, 5.5.2017, p. 1, ELI: <http://data.europa.eu/eli/reg/2017/745/oj>.

⁵ See Guidance - MDCG endorsed documents and other guidance https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en.