

EN

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Answer given by Mr Várhelyi  
on behalf of the European Commission  
(22.8.2025)

Artificial Intelligence (AI) systems intended for medical purposes are subject to several EU laws, including the Medical Devices Regulation (Regulation 2017/745)<sup>1</sup>, In Vitro Diagnostic Medical Devices Regulation (Regulation 2017/746)<sup>2</sup>, and the AI Act (Regulation 2024/1689)<sup>3</sup>. The AI Act under certain conditions classifies them as high-risk AI systems and sets out obligations for providers and deployers including on data quality and governance, transparency, human oversight, accuracy, robustness, and cybersecurity. The General Data Protection Regulation (Regulation 2016/679)<sup>4</sup> and, in the near future, the recently adopted European Health Data Space Regulation (Regulation 2025/327)<sup>5</sup> may also apply if personal data, including personal health data, are being processed.

Liability for damage caused by the use of AI is regulated by both EU and national laws. The Product Liability Directive (Directive 2024/2853)<sup>6</sup> provides that victims can seek compensation from manufacturers if harm is caused by defective products. Liability for the negligent use of AI is then regulated under national liability regimes.

The AI Act requirements on human oversight and transparency for high-risk AI systems aims to facilitate AI systems that are designed and used as tools that serve people, respect fundamental rights, health and safety, and remain subject to meaningful human control.

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<sup>1</sup> Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, OJ L 117, 5 May 2017, at 1; ELI: <http://data.europa.eu/eli/reg/2017/745/oj/eng>.

<sup>2</sup> Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices, OJ L 117, 5 May 2017, at 176; ELI: <http://data.europa.eu/eli/reg/2017/746/oj/eng>.

<sup>3</sup> Regulation (EU) 2024/1689 of 13 June 2024 laying down harmonised rules on artificial intelligence, OJ L 1689, 12 July 2024, at 1; ELI: <http://data.europa.eu/eli/reg/2024/1689/oj/eng>.

<sup>4</sup> Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, OJ L 119, 4 May 2016, at 1; ELI: <http://data.europa.eu/eli/reg/2016/679/oj/eng>.

<sup>5</sup> Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space, OJ L 327, 5 March 2025, at 1; ELI: <http://data.europa.eu/eli/reg/2025/327/oj/eng>.

<sup>6</sup> Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on liability for defective products, OJ L 2853, 18 November 2024, at 1; ELI: <http://data.europa.eu/eli/dir/2024/2853/oj/eng>.