WORLD TRADE ORGANIZATION

G/TBT/N/EU/1184

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** EUROPEAN UNION **If applicable, name of local government involved (Articles 3.2 and 7.2):**
2.	**Agency responsible:** European Commission EU-TBT Enquiry Point, Fax: +(32) 2 299 80 43, E-mail: grow-eu-tbt@ec.europa.eu Website: https://technical-barriers-trade.ec.europa.eu/en/home
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [X], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], Other:**
4.	**Products covered (HS codes or national tariff lines. ICS numbers may be provided in addition, where applicable):** Medical devices and *in vitro* diagnostic medical devices
5.	**Details of notified document(s) (title, number of pages and languages, means of access):** Commission proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and *in vitro* diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I, COM(2025)1023 final of 16.12.2025; (170 page(s), in English), (46 page(s), in English) **Link to notified document(s) and/or contact details for agency or authority which can provide copies upon request:** https://members.wto.org/crnattachments/2026/TBT/EEC/26_00369_00_e.pdf https://members.wto.org/crnattachments/2026/TBT/EEC/26_00369_01_e.pdf European Commission EU-TBT Enquiry Point Fax: + (32) 2 299 80 43 E-mail: grow-eu-tbt@ec.europa.eu The text is available on the Website: https://technical-barriers-trade.ec.europa.eu/en/home
6.	**Description of content:** Regulation (EU) 2017/745 on medical devices (MD Regulation) and Regulation (EU) 2017/746 on in vitro diagnostics medical devices (IVD Regulation) establish a new regulatory framework for medical devices and *in vitro* diagnostic medical devices. Their objectives are a high level of protection of health for patients and users and the smooth functioning of the internal market for these products. The MD Regulation has been applicable since 26 May 2021. It was notified to the WTO as notification G/TBT/N/EU/71. In March 2023, the European Parliament and the Council adopted a staggered extension of its transition period, ranging from 31 December 2027 for high risk devices to 31 December 2028 for medium and lower risk devices. It was notified

to the WTO as notification G/TBT/N/EU/943.

The IVD Regulation has been applicable since 26 May 2022. It was notified to the WTO as notification G/TBT/N/EU/72. In January 2022 and in July 2024, the European Parliament and the Council adopted a staggered extension of its transition periods, ranging from 31 December 2027 for high risk *in vitro* diagnostics to 31 December 2029 for lower risk *in vitro* diagnostics. They were notified to the WTO as notification G/TBT/N/EU/845 and G/TBT/N/EU/1044.

Despite considerable progress made over the past years, multiple challenges regarding the implementation of the Regulations on medical devices and in vitro diagnostics, persist. The notified proposal is the immediate follow up of the targeted evaluation of the EU regulatory framework for medical devices conducted by the European Commission in 2024/25. The notified proposal aims to streamline and future-proof the regulatory framework. Its main objective is to simplify rules, reduce the administrative burden on manufacturers and enhance the predictability and cost-efficiency of the certification procedure by notified bodies, while preserving a high level of public health protection and patient safety.

The notified proposal aims to

- reduce the administrative burden including reporting obligations;
- enhance the predictability and cost-efficiency of the certification processes of notified bodies;
- make the conformity assessment requirements more proportionate, especially for low- and medium-risk devices;
- adapt conformity assessment procedures to the needs of breakthrough technology devices or orphan devices;
- enable further digitalisation;
- streamline procedures including those on governance and enhance availability of external expertise for evidence-based decision-making;
- enable the EU medical device sector to benefit from international cooperation including reliance, where appropriate;
- enhance coherence of the requirements throughout the Regulations and with other Union legislation.

7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety; cost saving and productivity enhancement; harmonization.

The notified draft maintains and supports achievement of the initial objectives of Regulations (EU) 2017/745 and (EU) 2017/746 which are to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices and for *in vitro* diagnostic medical devices, ensuring a high level of safety and health whilst supporting innovation. They aim to ensure the smooth functioning of the internal market, taking as a base a high level of protection of health for patients and users, and taking into account the small-and medium-size enterprises that are active in this sector.; Protection of human health or safety; Harmonization; Cost saving and productivity enhancement

8. Relevant documents:

Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and in vitro diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I - COM/2025/1023 final

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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). EUR-Lex - 02017R0745-20200424 - EN - EUR-Lex (europa.eu) 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). EUR-Lex - 02017R0746-20170505 - EN - EUR-Lex (europa.eu)
9.	**Proposed date of adoption:** 2026 **Proposed date of entry into force:** 20 days after its publication in the Official Journal of the European Union
10.	**Provision of comments** **Final date for comments:** 16 April 2026 (90 days from notification) **[ ] 60 days from notification** **Contact details of agency or authority designated to handle comments regarding the notification:** European Commission, EU-TBT Enquiry Point, Fax: + (32) 2 299 80 43, E-mail: grow-eu-tbt@ec.europa.eu