NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** EUROPEAN UNION**If applicable, name of local government involved (Article 3.2 and 7.2):**  |
| **2.** | **Agency responsible:** European Commission**Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:** European Commission,EU-TBT Enquiry Point,Fax: +(32) 2 299 80 43,E-mail: grow-eu-tbt@ec.europa.euWebsite: [http://ec.europa.eu/growth/tools-databases/tbt/en/](http://ec.europa.eu/growth/tools-databases/tbt/en/%22%20%5Ct%20%22_blank) |
| **3.** | **Notified under Article 2.9.2 [****X],** **2.10.1 [****],** **5.6.2 [****],** **5.7.1 [****], 3.2 [****], 7.2 [****],** **other****:**  |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Medical devices and *in vitro* diagnostic medical devices |
| **5.** | **Title, number of pages and language(s) of the notified document:** Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices (COM(2023) 10 final); (15 page(s), in English) |
| **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 provides for a transition period that will end on 26 May 2024. It was notified to the WTO as notification [G/TBT/N/EU/71.](https://eping.wto.org/en/Search/Index?domainIds=1&countryIds=U918&freeText=medical%20devices&viewData=G%2FTBT%2FN%2FEU%2F71)The IVD Regulation has been applicable since 26 May 2022. It was notified to the WTO as notification [G/TBT/N/EU/72](http://tbtims.wto.org/en/RegularNotifications/View/107294?FromAllNotifications=True). In January 2022, the European Parliament and the Council adopted a staggered extension of its transition period, ranging from 26 May 2025 for high risk *in vitro* diagnostics to 26 May 2027 for lower risk *in vitro* diagnostics. It was notified to the WTO as notification [G/TBT/N/EU/845](https://eping.wto.org/en/Search/Index?domainIds=1&countryIds=U918&freeText=medical%20devices&viewData=G%2FTBT%2FN%2FEU%2F845).Despite considerable progress over the past years, the capacities of conformity assessment ('notified') bodies remain insufficient and manufacturers are not sufficiently prepared to meet the strengthened requirements of the MD Regulation on time. This is threatening the availability of medical devices on the EU market. The situation is exacerbated by the impact of the COVID-19 pandemic on clinical investigations, on-site audits and global supply chains.This proposal aims to extend the current transition period laid down in Article 120 of the MD Regulation, based on certain conditions. The conditions would ensure that only devices that are safe and for which manufacturers have already taken steps to transition to the MDR will benefit from the additional time. This would give manufacturers and notified bodies more time to conduct the conformity assessment procedures in accordance with the MDR, if those conditions are fulfilled. The draft measure proposes a staggered extension of the transition period depending on the risk class of the device, i.e. until 2027 for devices with a higher risk and until 2028 for medium and lower risk devices. The extension of the transition period is complemented by an extension of the validity of certificates issued under the previous Council Directives 90/385/EEC and 93/42/EEC for the devices benefiting from the extended transition period. Also the validity of certificates that have already expired since 26 May 2021 would be extended.It also proposes to remove the provisions in the MD Regulation and in the IVD Regulation on the 'sell-off' date, i.e. the end date for the further making available of devices which are placed on the market before or during the transition period and which are still in the supply chain when the transition period is over. This would prevent unnecessary disposal of safe medical devices, which are already on the market but not yet with the final user. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** The draft measure maintains the objectives of Regulations (EU) 2017/745 and (EU) 2017/746 to ensure a high level of safety and performance of devices by enhancing their oversight by notified bodies.It only provides for the necessary additional time to achieve this objective whilst ensuring the protection of human health and safety, in particular to prevent shortages of medical devices.Having regard to the usual length of conformity assessment procedures, the amendment to Regulation 2017/745 needs to be adopted as quickly as possible in order to ensure legal certainty for all actors, including manufacturers and notified bodies, ahead of the date on which the current transition period will end (26 May 2024).Therefore, given that this notified draft only amends the previously notified measures (Regulation (EU) 2017/745 and Regulation (EU) 2017/746) by extending its transitional provisions' scope and timelines, a reduced commenting period is justified; Protection of human health or safety |
| **8.** | **Relevant documents:** 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)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02017R0745-20200424)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)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02017R0746-20170505) |
| **9.** | **Proposed date of adoption:** February/March 2023 (as early as possible)**Proposed date of entry into force:** On the day of its publication in the Official Journal of the European Union |
| **10.** | **Final date for comments:** 10 days from notification |
| **11.** | **Texts available from: National enquiry point [****]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:** European Commission,EU-TBT Enquiry Point,Fax: + (32) 2 299 80 43,E-mail: grow-eu-tbt@ec.europa.euThe text is available on the EU-TBT Website : <http://ec.europa.eu/growth/tools-databases/tbt/en/><https://members.wto.org/crnattachments/2023/TBT/EEC/23_0277_00_e.pdf> |