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/> |
| **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):** Certain products without an intended medical purpose listed in Annex XVI of Regulation (EU) 2017/745 on medical devices and standard and made to order contact lenses. |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft Commission Delegated Regulation amending Regulation (EU) 2017/745 of the European Parliament and of the Council, as regards the assignment of Unique Device Identifiers for contact lenses; (7 page(s), in English) |
| **6.** | **Description of content:** The proposed Regulation is a Delegated measure adopted pursuant to Article 27 (10) (b) of Regulation (EU) 2017/745 whereby the Commission is empowered to amend Annex VI of that Regulation in light of international developments and technical progress in the field of Unique Device Identification. In order to resolve the implementation issue concerning the registration of UDI-DI data elements in Eudamed for highly individualised devices, and in particular contact lenses, the Commission is empowered to establish a specific UDI-DI assignment rule for such devices. This solution will allow a more effective implementation of the UDI system at European level. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Commission Regulations (EU) 2017/745 and (EU) 2017/746 introduced the Unique Device Identification (UDI) system, aiming at ensuring an adequate level of traceability with respect to medical devices and in vitro diagnostic medical devices.UDI comprises UDI-DIs and UDI-PIs, which shall be assigned (in compliance with the rules of the designated issuing entities), by manufacturers to all devices, other than custom-made devices, prior to the placement on the market.To further strengthen and enhance traceability and recording of UDIs, manufacturers have the obligation to report the UDI in Eudamed.However, for certain devices characterised by a high level of individualisation ('highly individualised devices'), a high variety of types and possible clinical parameters combinations would result in the assignment and reporting of a disproportionately high number of UDI-DIs for the same device model, with very limited value for regulatory purposes.The MDR does not provide for the possibility to exempt the manufacturers from the obligation of reporting UDI-DIs to Eudamed.Therefore, in order to resolve such implementation issue and limit the UDI-DI data entries in Eudamed, it is necessary to elaborate a solution that allows the grouping of highly individualised devices presenting specific similarities with respect to defined clinically relevant parameters under a same UDI-DI identifier (the 'Master UDI-DI')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 2011/83/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, 5.2017, p. 1-175).<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745> |
| **9.** | **Proposed date of adoption:** 4th quarter 2023**Proposed date of entry into force:** The twentieth day following its publication in the Official Journal of the EU |
| **10.** | **Final date for comments:** 60 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_8501_00_e.pdf> |