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 [****],** **other****:**  |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Products without an intended medical purpose listed in Annex XVI of Regulation (EU) 2017/745 on medical devices. |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft Commission Implementing Regulation laying down common specifications for the groups of products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices (7 page(s), in English; 35 page(s), in English) |
| **6.** | **Description of content:** The common specifications (CS) for each of the groups of products listed in Annex XVI of Regulation (EU) 2017/745 on medical devices address the application of risk management, in respect of certain general safety and performance requirements set out in Annex I of that Regulation. Examples for those Annex XVI products are cosmetic contact lenses; implants without medical purpose; facial, dermal or mucous membrane fillers; liposuction equipment; intense pulsed light or laser equipment for hair removal and brain stimulators. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Products without an intended medical purpose listed in Annex XVI of Regulation (EU) 2017/745 will be regulated for the first time under the medical device legislation from the date of application of the common specifications. Therefore, the adoption of the common specifications is awaited by manufacturers of products without an intended medical purpose as well as notified bodies intended to be designated to carry out the relevant conformity assessment procedures. The sooner the common specifications are adopted, the sooner the medical device regulation will cover also the products without an intended medical purpose, significantly enhancing the harmonisation of the internal market and the safety of the products covered. 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:** 2nd quarter 2022**Proposed date of entry into force:** 20 days from publication in the Official Journal of the EU (The provisions shall apply as from six month after the date of their entering into force) |
| **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/2022/TBT/EEC/22_0408_00_e.pdf><https://members.wto.org/crnattachments/2022/TBT/EEC/22_0408_01_e.pdf> |