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: Preventing International Trade Barriers | TBT - European Commission |
| **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 |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft Commission Implementing Regulation amending Implementing Regulation (EU) 2021/2226 as regards the medical devices for which the instructions for use may be provided in electronic form; (3 page(s), in English) |
| **6.** | **Description of content:** This draft Commission Implementing Regulation expands the scope of the possibility to provide electronic instructions for use to all devices intended for exclusive use by healthcare professionals in accordance with Annex I, Chapter III, point 23.1(f), to Regulation (EU) 2017/745. It also requires provision in EUDAMED of the URL to the electronic instructions for use.  |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** On the above legal basis, Commission Implementing Regulation (EU) 2021/2226 sets out the conditions under which information in the instructions for use, as defined by Article 2(14) of Regulation (EU) 2017/745 and detailed in Annex I, Chapter III, point 23.4 to Regulation (EU) 2017/745 may be provided by manufacturers in electronic form, as referred to in Annex I, Chapter III, point 23.1(f), to Regulation (EU) 2017/745. It also establishes certain requirements concerning contents of and websites for instructions for use that are provided in electronic form in addition to instructions for use in paper form.The present planned implementing act aims to amend Commission Implementing Regulation (EU) 2021/2226 to add the possibility to provide electronic instructions for use for all devices intended for exclusive use by professional users; Protection of human health or safety |
| **8.** | **Relevant documents:** Commission Implementing Regulation (EU) 2021/2226 of 14 December 2021 laying down rules for the application of Regulation (EU) 2017/745 as regards electronic instructions for use of medical devices of the European Parliament and of the Council, OJ L 448, 15.12.2021, p. 32:<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R2226>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. 176:<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745> |
| **9.** | **Proposed date of adoption:** 2nd Quarter 2025**Proposed date of entry into force:** 20 days from 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 : <https://technical-barriers-trade.ec.europa.eu/en/home><https://members.wto.org/crnattachments/2025/TBT/EEC/25_01853_00_e.pdf> |