NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** Ukraine **If applicable, name of local government involved (Article 3.2 and 7.2):**  |
| **2.** | **Agency responsible:** Ministry of Health of Ukraine **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:**  |
| **3.** | **Notified under Article 2.9.2 [****X],** **2.10.1 [****],** **5.6.2 [****X],** **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):** Medical devices, in vitro diagnostic medical devices, active implantable medical devices |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft Order of the Ministry of Health of Ukraine "On approval of the Procedure for putting into circulation and operation of certain medical devices, in vitro diagnostic medical devices and active implantable medical devices, in respect of which the requirements of technical regulations are not fulfilled, but the use of which is necessary in the interests of health care" (9 page(s), in Ukrainian) |
| **6.** | **Description of content:** The draft Order provides that certain medical devices, in vitro diagnostic devices and active implantable medical devices, in respect of which the requirements of technical regulations are not fulfilled, but the use of which is necessary in the interests of health care, may be put into circulation and operation without right of their sale in cases:- participation in international technical assistance programs;- emergency situation;- individual use and/or exploitation by individuals for the purpose of preserving their life and health;- medical support (medical application) of military servicemen and persons in the rank and file and commanding officers who execute tasks during the fulfilment the activity to ensure national security and defence during the military activities, emergency state, special period;- medical care for units of the armed forces of other states, which are admitted to the territory of Ukraine in accordance with the legislation;- humanitarian aid. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety |
| **8.** | **Relevant documents:** * Technical Regulation on medical devices, approved by the Resolution of the Cabinet of Ministers of Ukraine of 02.10.2013 No.753, available in Ukrainian
* Technical Regulation on in vitro diagnostic medical devices, approved by the Resolution of the Cabinet of Ministers of Ukraine of 02.10.2013 No.754, available in Ukrainian
* Technical Regulation on active implantable medical devices, approved by the Resolution of the Cabinet of Ministers of Ukraine of 02.10.2013 No.755, available in Ukrainian
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| **9.** | **Proposed date of adoption:** To be determined **Proposed date of entry into force:** From the date of its official publication |
| **10.** | **Final date for comments:** 60 days from notification |
| **11.** | **Texts available from: National enquiry point [****X]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:** The text is available at the official web-site of the Ministry of Health of Ukraine:<https://moz.gov.ua/article/public-discussions/proekt-nakazu-ministerstva-ohoroni-zdorovja-ukraini-pro-zatverdzhennja-porjadku-vvedennja-v-obig-ta-ekspluataciju-okremih-medichnih-virobiv-medichnih-virobiv-dlja-diagnostiki-in-vitro-ta-aktivnih-medichnih-virobiv><https://members.wto.org/crnattachments/2020/TBT/UKR/20_4485_00_x.pdf><https://members.wto.org/crnattachments/2020/TBT/UKR/20_4485_01_x.pdf> |