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 Law of Ukraine "On Medical Devices" (9 page(s), in Ukrainian) |
| **6.** | **Description of content:**  the draft Law aims at:* elimination of ambiguous interpretation of the norms regarding classification of medical devices;
* reduction of the circulation of counterfeit medical devices;
* elimination of double proof of safety of medical devices (deregulation);
* regulation of advertising of medical devices;
* creation of legal grounds for the development of legal acts concerning clinical investigations and performance evaluation;
* determination of the legal grounds for taking market surveillance measures for all medical devices, regardless of the method of placing on the market;
* simplification of the conformity assessment procedure through the use of remote audits.
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| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** The purpose of the adoption of the Law of Ukraine "On Medical Devices" is to eliminate aspects of the circulation of medical devices that are not regulated by current legislation of Ukraine.; Prevention of deceptive practices and consumer protection; Protection of human health or safety |
| **8.** | **Relevant documents:** The Law of Ukraine "On technical regulations and conformity assessment",The Law of Ukraine "On Ensuring Sanitary and Epidemic Welfare of the Population",The Law of Ukraine "On medicines",The Law of Ukraine "On advertising",Resolution of the Cabinet of Ministers of Ukraine N 753 of 02 October 2013 "On approval of the Technical Regulation on medical devices",Resolution of the Cabinet of Ministers of Ukraine N 754 of 02 October 2013 "On approval of the Technical Regulation on in vitro diagnostic medical devices",Resolution of the Cabinet of Ministers of Ukraine N 755 of 02 October 2013 "On approval of the Technical Regulation on active implantable medical devices". |
| **9.** | **Proposed date of adoption:** To be determined **Proposed date of entry into force:** To be determined  |
| **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:** <https://moz.gov.ua/article/public-discussions/proekt-zakonu-ukraini-pro-medichni-virobi>  |