NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** Philippines **If applicable, name of local government involved (Article 3.2 and 7.2):**  |
| **2.** | **Agency responsible:** Department of Health - Food and Drug Administration**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:** Engr. Bayani C. San Juan, Director IVCenter for Device Regulation, Radiation Health, and Research (CDRRHR)Civic Drive, Filinvest Corporate City, Alabang 1781 Muntinlupa, Philippines+632.857.1900 loc 8301info@fda.gov.ph/eppayas@fda.gov.ph[www.fda.gov.ph](http://www.fda.gov.ph) |
| **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):** Medical equipment (ICS 11.040), In vitro diagnostic test systems (ICS 11.100.10) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft Administrative Order No. \_\_\_\_: Guidelines on the Labeling Requirements for Medical Devices in the Philippines (10 page(s), in English) |
| **6.** | **Description of content:** The Food and Drug Administration (FDA) through the Center for Device Regulation, Radiation Health and Research (CDRRHR) is the primary agency authorized to enforce regulatory requirement on manufacture, importation, distribution, sale, and offering for sale of medical devices in accordance with the provisions of Republic Act 9711 also known as FDA Act of 2009, its Implementing Rules and Regulations (IRR). As stipulated in the IRR, the CDRRHR is mandated to establish an effective regulatory system and mechanism to ensure the safety, quality and performance of medical devices in the Philippines.The Philippines as a signatory to the ASEAN Agreement on Medical Device Directive (AMDD), adheres to continuously harmonize the technical procedures and requirements to reduce diversity in the regulations of medical devices.The issuance of the guidelines on labeling requirements for medical devices, serves to communicate safety instructions related to information to users and/ or patients, as well as to standardize the required policy, and to assure the highest quality of medical devices used in the country. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** This Administrative Order aims to provide guidelines on the labeling requirements for medical devices aligned with the provisions of the ASEAN Medical Device Directive.Consumer information, labelling; Protection of human health or safety; Quality requirements |
| **8.** | **Relevant documents:** * Republic Act 9711 - Food and Drug Administration Act of 2009
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| **9.** | **Proposed date of adoption:** This Order shall take effect 15 days after its publication in a national newspaper of general circulation.**Proposed date of entry into force:** This Order shall take effect 15 days after its publication in a national newspaper of general circulation. |
| **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:** Center for Device Regulation, Radiation Health, and Research (CDRRHR)Civic Drive, Filinvest Corporate City, Alabang 1781 Muntinlupa, Philippines+632.857.1900 loc 8301info@fda.gov.ph/eppayas@fda.gov.ph[www.fda.gov.ph](http://www.fda.gov.ph)<https://members.wto.org/crnattachments/2019/TBT/PHL/19_1879_00_e.pdf> |