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 IV  Center for Device Regulation, Radiation Health, and Research (CDRRHR)  Civic Drive, Filinvest Corporate City, Alabang 1781 Muntinlupa, Philippines  +632.857.1900 loc 8301  [info@fda.gov.ph](mailto:info@fda.gov.ph)/[eppayas@fda.gov.ph](mailto: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):** 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. \_\_\_ : Rules and Regulations Governing the Issuance of an Authorization for an In-Vitro Diagnostic (IVD) Medical Device Based on the ASEAN Harmonized Technical Requirements (12 page(s), in English) |
| **6.** | **Description of content:** Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", and its Implementing Rules and Regulations, declare that it is the policy of the state to insure the safety, efficacy and quality of IVD medical devices in the country so as to protect the health of the Filipino people.  The signing of the ASEAN Agreement on Medical Device Directive (AMDD) in 2014, mandated the Philippines to implement the following provisions to a) "require the person responsible for placing the IVD medical devices in that Member State or the authorized representative to register the IVD medical devices with the regulatory authority by of that Member State", b) "shall undertake all necessary measures to ensure that only IVD medical devices which conform to the AMDD may be placed on markets of that Member State" and c) "put in place an appropriate system for the registration of IVD medical devices with the Regulatory Authority of that Member State".  The Department of Health through the Food and Drug Administration - Center for Device Regulation, Radiation Health and Research (CDRRHR) hereby adopt, issues and implement the AMDD guidelines on the registration of IVD medical devices and to provide the regulatory requirement and registration process. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** This Administrative Order aims to specify the rules, guidelines, procedures and requirements of the FDA-CDRRHR relative to the issuance of an authorizations for IVD medical devices adapting the provisions of ASEAN AMDD.  Protection of human health or safety |
| **8.** | **Relevant documents:**   * Republic Act No. 9711 - Food and Drug Administration Act of 2009 |
| **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 [** **]** **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 8301  [info@fda.gov.ph](mailto:info@fda.gov.ph)/[eppayas@fda.gov.ph](mailto:eppayas@fda.gov.ph)  [www.fda.gov.ph](http://www.fda.gov.ph)  <https://members.wto.org/crnattachments/2019/TBT/PHL/19_1876_00_e.pdf> |