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:**  FOOD AND DRUG ADMINISTRATION PHILIPPINES DEPARTMENT OF HEALTH  **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. Maria Cecilia C. Matienzo Director IV Center for Device Regulation, Radiation Health and Research (CDRRHR) Civic Drive Filinvest Corporate City Alabang, Muntinlupa City Tel. no: +632 8 857-1900 [mccmatienzo@fda.gov.ph](mailto:mccmatienzo@fda.gov.ph); [cdrrhr@fda.gov.ph](mailto:cdrrhr@fda.gov.ph); [cdrrhr-prsdd@fda.gov.ph](mailto:cdrrhr-prsdd@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 devices |
| **5.** | **Title, number of pages and language(s) of the notified document:** FDA Circular No. 2021-001 Hierarchy of Product Standards for Medical Devices to be Complied with for Notification/Registration Purposes (2 page(s), in English) |
| **6.** | **Description of content:** This Administrative Order was formulated to guide the local manufacturer, importer and/or distributor of medical devices regarding the product standards to conform prior to notification/registration with the Philippines' Food and Drug Administration as part of the implementation of Administrative Order No. 2018-0002: Guidelines Governing the Issuance of an Authorization for a Medical Device Based on the ASEAN Harmonized Technical Requirements. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety |
| **8.** | **Relevant documents:**   * Republic Act No. 9711 or Food and Drug Administration Act of 2009 * Implementing Rules and Regulation of Republic Act No. 9711 * Administrative Order No. 2018-002: Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements * FDA Circular No. 2021-001: Initial Implementation of Administrative Order No. 2018-0002 "Guidelines Governing the Issuance of an Authorization for a Medical Device Based on the ASEAN Harmonized Technical Requirements" |
| **9.** | **Proposed date of adoption:** Not applicable  **Proposed date of entry into force:** Not applicable |
| **10.** | **Final date for comments:** Not applicable |
| **11.** | **Texts available from: National enquiry point [** **]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:**  MR. NEIL P. CATAJAY Director Bureau of Philippine Standards Department of Trade and Industry 3F Trade and Industry Building 361 Sen. Gil Puyat Avenue Makati City, Philippines 1200  (632) 7751 4700; (632) 7751 4706 Email: [bps@dti.gov.ph](mailto:bps@dti.gov.ph)  <http://www.bps.dti.gov.ph>  <https://www.fda.gov.ph/wp-content/uploads/2021/01/FDA-Circular-No.2021-001.pdf> |