NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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; cddhr@fda.gov.ph; cddhr-psd@fda.gov.ph
   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

9. **Proposed date of adoption:** 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  
    http://www.bps.dti.gov.ph  