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):** Installations and equipment for waste disposal and treatment (ICS 13.030.40) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft Administrative Order No. \_\_\_ : Guidelines on the Issuance of an Authorization for Equipment or Devices Used for Treating Sharps, Pathological and Infectious Waste (14 page(s), in English) |
| **6.** | **Description of content:** The Department of Environment and Natural Resources (DENR) and the Department of Health (DOH) issued Joint DENR-DOH Administrative Order No. 02 series of 2005 to provide guidelines on the management of health care wastes relative to the Implementing Rules and Regulations (IRR) of Chapter XVIII - "Refuse Disposal" of the Code on Sanitation of the Philippines (P.D. 856).The Joint DENR-DOH Administrative Order mandated the DOH to require all health care waste treatment, storage, disposal (TSD) facility operators and health care waste generators with on-site waste treatment facilities to use DOH registered equipment or devices used for treatment of health care wastes.On 14 March 2007, Administrative Order No. 2007-0014 was issued by the Secretary of Health through the Bureau of Health Devices and Technology (BHDT) to provide guidelines on the rules and regulations with respect to registration, monitoring and evaluation of devices and equipment used in the treatment of sharps, pathological and infectious wastes.Republic Act 9711, otherwise known as the "Food and Drug Administration (FDA) Act of 2009" through its IRR enhance, strengthen and rationalize the regulatory systems for establishment and products under its jurisdictions.To effectively implement the above provisions on the regulations of all devices and equipment used in the treatment of sharps, pathological and infectious wastes in the Philippines, the FDA-Center for Device Regulation, Radiation Health, and Research (CDRRHR) (formerly BHDT) hereby issues this Administrative Order. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** This Administrative Order aims to enhance and strengthen the existing rules and regulations of the FDA-CDRRHR relative to safety, efficacy and quality of equipment or devices used for treating sharps, pathological and infectious wastes. Protection of human health or safety |
| **8.** | **Relevant documents:** * P.D. 856 - Code on Sanitation of the Philippines
* Administrative Order No. 2007-0014
* 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_1878_00_e.pdf> |