07 August 2024

NOTICE TO RELEVANT STAKEHOLDERS

Dear Sir/Ma'am:

This refers to the draft regulations distributed through the World Trade Organization – Technical Barriers to Trade (WTO-TBT) website (www.epingalert.org) from 27 July to 02 August 2024.

Relative thereto, we respectfully invite stakeholders to comment on the notified draft technical regulations from China, Équateur, Mexique and United States:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/CHN/1878	China	**Date of Distribution:** 1 August 2024 **Deadline for Comments:** 30 September 2024	Radiation : requirements for development, validation and routine control of a sterilization process for medical devices	This document specifies the requirements for the development, validation, and routine control of medical devices during radiation sterilization processes. This document applies to medical devices, but these requirements and provided guidelines can be applied to other products and devices.
G/TBT/N/ECU/522/Add.1	Équateur	**Date of Distribution:** 1 August 2024 **Deadline for Comments:** Not indicated	Pharmaceutical products containing new chemical entities - Addendum	Technical Health Regulations to grant the period of exclusivity of test data for Pharmaceutical Products that contain new chemical entities. The Republic of Ecuador communicates and makes known Addendum 1 corresponding to the Technical Health Regulations to grant the period of exclusivity of test data of Pharmaceutical Products Containing New Chemical Entities, which aims to establish the requirements and procedure by which ARCSA will grant a period of exclusivity of test data or other undisclosed information on safety and efficacy, for pharmaceutical products containing new entities. chemicals.
G/TBT/N/MEX/534	Mexique	**Date of Distribution:** 1 August 2024 **Deadline for Comments:** 30 September 2024	Manufacture medical devices	This draft Standard aims to establish the minimum requirements for the design, development, manufacturing, storage and distribution processes of medical devices for human use, based on their risk level; that are marketed and made available in national territory with the purpose of ensuring that they consistently comply with the quality, safety and performance requirements to be used by the final consumer or patient.

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Membership:
- International Organization for Standardization (ISO)
- International Electrotechnical Commission (IEC)
- World Trade Organization (WTO) Technical Barriers to Trade (TBT)
  - National Enquiry Point (NEP)
  - National Notification Authority (NNA)

G/TBT/N/USA/1260/Rev.1/Add.2	United States	**Date of Distribution:** 31 July 2024 **Deadline for Comments:** Not indicated	Medical diagnostic equipment - Addendum	The Architectural and Transportation Barriers Compliance Board (hereafter, “Access Board” or “Board”), is issuing this final rule to remove the sunset provisions in the Board's existing accessibility standards for medical diagnostic equipment related to the low height specifications for transfer surfaces, and replace them with a final specification for the low transfer height of medical diagnostic equipment used in the supine, prone, side-lying, and the seated position.

To access the notification form, right click the document symbol to open the hyperlink. Should you have any queries on this matter or request for full text of draft regulation in English, please do not hesitate to email us at BPS@dti.gov.ph copy bps.smd@dti.gov.ph.

Thank you.

Sincerely,

Digitally signed by
Catajay Neil
Pinuela

NEIL P. CATAJAY
Director

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