

26 February 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 10 to 16 February 2024.

Relative thereto, we respectfully invite stakeholders to comment on the seven (7) notified draft technical regulations from Chile, China, Egypt, Republic of Korea, and Uganda:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/NC/HL/598/Ad.d.3	Chile	Date of Distribution: 16 February 2024 Deadline for Comments: Not Indicated	Medical devices to detect human immunodeficiency virus (HIV) - Addendum	Exempt Decree No. 41 of the Ministry of Health, dated June 8, 2022: Incorporates the health control regime established in article 111 of the Sanitary Code, to the devices for HIV screening indicating (Ministry of Health Exempt Decree No. 41 of 8 June 2022 adding the indicated devices for HIV detection to the health control system established in Article 111 of the Health Code)
G/TBT/NC/HL/673	Chile	Date of Distribution: 13 February 2024 Deadline for Comments: 12 April 2024	Finished pharmaceutical products	The notified guide seeks to contribute to establishing a set of comprehensive specifications for pharmaceutical products. It provides guidance on establishing and justifying acceptance criteria, and selecting analytical testing procedures for pharmaceutical products produced from active substances of synthetic or biological origin. Pursuant to Ministry of Health Supreme Decree No. 3 of 2010, approving the Regulations of the National Control System for Products for Human Use, the specifications are set out in a technical document that defines the attributes of a raw material, material, product, service or other, and determines which of their variables must be evaluated, describing all the tests, trials and analyses used to determine and

BUREAU OF PHILIPPINE STANDARDS

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)

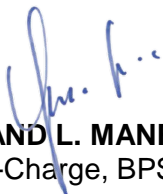
				establish the acceptance or rejection criteria (Article 5(29)).
G/TBT/N/C HN/1820	China	Date of Distribution: 12 February 2024 Deadline for Comments: 11 April 2024	Automated washer-disinfector	This document specifies the performance requirements, control requirements, hygienic indicators and detection methods, transportation, storage and packaging, identification, nameplates and instructions for the use of automated washer disinfector for endoscope. This document applies to automated washer-disinfector for flexible endoscope.
G/TBT/N/E GY/349/Ad d.1	Egypt	Date of Distribution: 15 February 2024 Deadline for Comments: Not Indicated	Medical electrical equipment : infant incubators - Addendum	This addendum concerns the notification of the Ministerial Decree No. 499 /2023 (4 pages, in Arabic) that gives producers and importers a six-month transitional period to abide the Egyptian Standard ES 4940 for "Medical electrical equipment - Particular requirements for the basic safety and essential performance of infant incubators "(40 pages, in Arabic). It should be noted that the draft of this standard was formerly notified in G/TBT/N/EGY/349 dated 8 March 2023. Worth mentioning is that this standard is technically identical with IEC 60601-2-19:2020. Producers and importers are kept informed of any amendments in the Egyptian standards through the publication of administrative orders in the official gazette.
G/TBT/N/E GY/413	Egypt	Date of Distribution: 15 February 2024 Deadline for Comments: 14 April 2024	Metallic skeletal pins and wires for use in bone surgery	The Ministerial Decree No. 499 /2023 gives producers and importers a six-month transitional period to abide by the Egyptian standard ES 6786-1 which specifies general requirements for metallic skeletal pins and wires for use in bone surgery, excluding wires for binding and twisting. This standard cancels and supersedes its last edition issued ES 6786-1/2008 Worth mentioning is that this standard is technically identical with ISO 5838-1/2013
G/TBT/N/K OR/1199	Republic of Korea	Date of Distribution:	Medical devices	The proposed amendments to the "Regulation on medical

		16 February 2024 Deadline for Comments: 15 April 2024		device group and class by group" is as follows: 1) Establishment of the technology levels of autonomous driving electric wheelchair - Establishment of new standards to create a basis for classifying autonomous driving electric wheelchairs, taking into account their place of use and technical functionalities such as location determination, map formation, route creation, etc. 2) Establishment of new items - Establishment of 42 new items for medical devices to categorize those developed within the industry and formalize temporarily designated items 3) Adjustment of the class of medical devices - The class of 8 items was adjusted considering international harmonization and equity with other medical devices. 4) Change in item name (including English name) and definition. - Two item names or definitions were changed based on item subdivision and considerations regarding clinical use environments.
G/TBT/N/UGA/1245/Add.3	Uganda	Date of Distribution: 12 February 2024 Deadline for Comments: Not Indicated	Medical cotton swabs - Addendum	The aim of this addendum is to update WTO Members that the Draft Uganda Standard; DUS 2276:2020, Medical cotton swabs — Specification, First Edition; notified in G/TBT/N/UGA/1245, G/TBT/N/UGA/1245/Add.1 and G/TBT/N/UGA/1245/Add.2 was withdrawn on 1 December 2023.

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,



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