12 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 27 January to 02 February 2024.

Relative thereto, we respectfully invite stakeholders to comment on the ten (10) notified draft technical regulations from five (5) WTO Members:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/BDI/175/Add.2	Burundi	**Date of Distribution**: 02 February 2024 **Deadline for Comments**: Not Indicated	Medical cotton swabs - Addendum	The aim of this addendum is to update WTO Members that the Draft East African Standard, DEAS 1070:2021, Medical cotton swabs — Specification, First Edition. notified in G/TBT/N/BDI/175, G/TBT/N/RWA/566, G/TBT/N/BDI/175/Add.1, G/TBT/N/TZA/663, G/TBT/N/RWA/566/Add.1, G/TBT/N/UGA/1497, G/TBT/N/TZA/663/Add.1 and G/TBT/N/UGA/1497/Add.1 entered into force in Uganda on 1 December 2023. The Uganda Standard, EAS 1070:2022, Medical cotton swabs — Specification, First Edition, can be purchased online through the link: https://webstore.unbs.go.ug/
G/TBT/N/BDI/176/Add.2	Burundi	**Date of Distribution**: 02 February 2024 **Deadline for Comments**: Not Indicated	Cotton ear buds - Addendum	The aim of this addendum is to update WTO Members that the Draft East African Standard, DEAS 1069:2021, Cotton ear bud — Specification, First Edition notified in G/TBT/N/BDI/176, G/TBT/N/RWA/567, G/TBT/N/BDI/176/Add.1, G/TBT/N/TZA/664, G/TBT/N/RWA/567/Add.1, G/TBT/N/UGA/1498, G/TBT/N/TZA/664/Add.1 and G/TBT/N/UGA/1498/Add.1 entered into force in Uganda on 1 December 2023. The Uganda Standard, US EAS 1069:2022, Cotton ear bud — Specification, First Edition, can be purchased online through the link: https://webstore.unbs.go.ug/

3/F Trade and Industry Building
361 Sen. Gil Puyat Avenue, Makati City, 1200 Philippines
Phone/ (632) 7791.3331 / 7791.3128
E-mail: bps@dti.gov.ph • Website: www.bps.dti.gov.ph

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/CRI/71/Add.4	Costa Rica	**Date of Distribution**: 30 January 2024 **Deadline for Comments**: Not Indicated	Biomedical equipment and material - Addendum	The purpose of this amendment is to facilitate trade and to make the process for submitting a Certificate of Free Sale (CFS) more flexible so that, in the case of manufactures by third parties or subsidiaries and when the product is not marketed in the country of manufacture, the CFS may be issued by the competent authority of the country where a subsidiary of the company proprietor of the biomedical equipment and material (BEM) or of the parent company is located. The subsidiary must be duly incorporated and not only registered with the competent authority of the country of the proprietor of the product. It also promotes the efficient review of BEM labels, so that there are no further delays in the procedure for assessing post-registration changes. To that end, Transitional Clause III has been extended from 6 months. When a product is subject to recognition of equivalence of the conformity assessment systems of the registration systems, and a CFS is submitted issued by the authority of a country with which no recognition agreement is in place, the notified document clarifies that missing elements must be submitted to complete the file, in order to ensure the efficient review of the label and avoid further delays. This is quite logical, but to avoid misunderstandings, it was decided to provide clarification in the interest of the principle of clear and unambiguous rules.
G/TBT/N/CRI/71/Add.4/Corr.1	Costa Rica	**Date of Distribution**: 01 February 2024 **Deadline for Comments**: Not Indicated	Biomedical equipment and material- Corrigendum	RTCR No. 405:2007 "Regulations for the Registration, Classification, Importation and Inspection of Biomedical Equipment and Material" Please note that the following text should be added at the end of the Description: A 30-day comment period has been established.
G/TBT/N/EGY/261/Add.2	Egypt	**Date of Distribution**: 30 January 2024	Manually powered suction equipment	This addendum concerns the notification of the Ministerial Decree No. 499 /2023 (4 pages, in Arabic) that gives the

		Deadline for Comments: Not Indicated	intended for oro-pharyngeal suction - Addendum	producers and importers a six-month transitional period to abide by the Egyptian Standard ES 6134-2 for " Medical Suction Equipment Part 2: Manually Powered Suction Equipment " (8 page(s), in Arabic) It should be noted that the draft of this standard was formerly notified in G/TBT/N/EGY/261/Add.1 dated 8 March 2023.
G/TBT/N/EGY/262/Add.2	Egypt	**Date of Distribution**: 30 January 2024 **Deadline for Comments**: Not Indicated	Medical suction equipment powered from a vacuum or positive pressure gas source generating venturi suction - Addendum	This addendum concerns the notification of the Ministerial Decree No. 499 /2023 (4 pages, in Arabic) that gives the producers and importers a six-month transitional period to abide by the Egyptian Standard ES 6134-3 for "Medical Suction Equipment Part: 3- Suction equipment powered from a vacuum or positive pressure gas source" (8 page(s), in Arabic) It should be noted that the draft of this standard was formerly notified in G/TBT/N/EGY/262/Add.1 dated 8 March 2023
G/TBT/N/EGY/346/Add.1	Egypt	**Date of Distribution**: 30 January 2024 **Deadline for Comments**: Not Indicated	Medical suction equipment - Addendum	This addendum concerns the notification of the Ministerial Decree No.502/2023 (4 pages, in Arabic) that gives the producers and importers a six-month transitional period to abide by the Egyptian Standard ES 6134-4 for "Medical Suction Equipment - Part 4: General requirements"; (43 page(s), in Arabic) It should be noted that the draft of this standard was formerly notified in G/TBT/N/EGY/346 dated 8 March 2023 Worth mentioning is that this standard is technically identical with ISO 10079-4/2021.
G/TBT/N/EGY/347/Add.1	Egypt	**Date of Distribution**: 30 January 2024 **Deadline for Comments**: Not Indicated	Medical suction equipment : electrically powered suction equipment - Addendum	This addendum concerns the notification of the Ministerial Decree No.502/2023 (4 pages, in Arabic) that gives the producers and importers a six-month transitional period to abide by the Egyptian Standard ES 6134-1 for "Medical Suction Equipment Part 1: Electrically Powered Suction Equipment" (9 page(s), in Arabic). It should be noted that the draft of

				this standard was formerly notified in G/TBT/N/EGY/347 dated 8 March 2023. This standard cancels and supersedes its last edition ES 6134-1:2008. Worth mentioning is that this standard is technically identical with ISO 10079-1/2022.
G/TBT/N/EU/1044	European Union	**Date of Distribution**: 31 January 2024 **Deadline for Comments**: 19 February 2024	Medical devices and in vitro diagnostic medical devices	Regulation (EU) 2017/745 on medical devices (MD Regulation) and Regulation (EU) 2017/746 on in vitro diagnostics medical devices (IVD Regulation) establish a new regulatory framework for medical devices and in vitro diagnostic medical devices. Their objectives are a high level of protection of health for patients and users and the smooth functioning of the internal market for these products.
G/TBT/N/UKR/285	Ukraine	**Date of Distribution**: 02 February 2024 **Deadline for Comments**: 01 April 2024	Medicinal products	The draft Resolution of the Cabinet of Ministers of Ukraine "Some Issues of Safety and Verification of Medicinal Products" is developed in order to establish and ensure the effective operation of the national system of verification of medicinal products and to assure that manufacturers apply safety features to the packaging of the medicinal product. In order to approximate the EU legislation on preventing and combating the circulation of counterfeit medicines and to effectively prevent and combat the circulation of counterfeit medicines it is proposed to implement the verification of medicines - the 2D coding system for medicines.

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