

27 July 2023

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 17 to 21 July 2023.

Relative thereto, we respectfully invite stakeholders to comment on the five (5) notified draft technical regulations from four (4) WTO Members:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/CH/N/1736	China	Date of Distribution: 20 July 2023 Deadline for Comments: 17 September 2023	Positive pressure self-contained closed-circuit breathing apparatus of compressed oxygen	This document specifies the technical requirements, test methods, classification, inspection rules, marking, packaging, storage and transportation requirements for positive pressure self-contained closed-circuit compressed oxygen breathing apparatus and compressed oxygen-nitrogen breathing apparatus (hereinafter referred to as oxygen breathing apparatus). This document applies to self-contained closed-circuit compressed oxygen breathing apparatus and compressed oxygen-nitrogen breathing apparatus used in the positive pressure air supply mode. This document does not apply to negative pressure oxygen breathing apparatus, air breathing apparatus, diving breathing apparatus, escape oxygen breathing apparatus, compressed oxygen self-rescue apparatus and chemical oxygen breathing apparatus.
G/TBT/N/CH/N/1739	China	Date of Distribution: 20 July 2023 Deadline for Comments:	Service of prostheses fitting	The document specifies service requirements for fitting prosthesis, such as reception, examination, signing the agreements, prescription, fitting cycle, rehabilitation training before fabrication, fabrication, training for

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)

		17 September 2023		use of prosthesis, quality inspection of fitting, delivery, after-sale service. The document applies to all the organizations engaged in prosthesis fitting.
G/TBT/N/PE R/137/Add.1	Peru	Date of Distribution: 20 July 2023 Deadline for Comments: Not Indicated	Drugs and Biologicals - Addendum	By means of Supreme Decree No. 020-2023-SA, the Regulations for the Conditional Sanitary Registration of Medicines and Biological Products, which will enter into force six (6) months from the day after its publication in the Official Gazette El Peruano; likewise, repeals Supreme Decree No. 002-2021-SA and its amendment approved by Decree Supreme Court No. 019-2021-SA.
G/TBT/N/SL V/228	El Salvador	Date of Distribution: 19 July 2023 Deadline for Comments: 16 September 2023	Medical devices	This Salvadoran Technical Regulation establishes the technical provisions for the development and execution of technovigilance at the national level, according to the current legal framework and internationally harmonized principles in the subject; that allow the identification, registration, evaluation, follow-up and disclosure of the information related to events and adverse incidents produced by the failure of a medical device, as well as quality irregularities and non-compliance with the current health legislation applicable to these health technologies.
G/TBT/N/TP KM/527	The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu	Date of Distribution: 18 July 2023 Deadline for Comments: 15 September 2023	Medical equipment	In view of the ever-changing nature and the variety of medical devices, the FDA proposes to amend the regulations which govern the approval and listing of medical devices to align its approaches with the international ones and improve administrative efficiency.

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,

NEIL P. CATAJAY
Director

A handwritten signature in blue ink, appearing to be 'N. Catajay', is positioned to the right of the typed name and title.