

21 March 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](http://www.epingalert.org)) from 04 to 10 March 2023.

Relative thereto, we respectfully invite stakeholders to comment on the twelve (12) notified draft technical regulations from Brazil, Egypt, Peru, and Philippines:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
<a href="#">G/TBT/N/BRA/835/Ad d.2/Corr.1</a>	Brazil	<b>Date of Distribution:</b> 08 March 2023  <b>Deadline for Comments:</b> Not Indicated	Thermometers - Corrigendum	Rectification of subitem 7.1.3 of the Metrological Technical Regulation (RTM) attached to Inmetro Ordinance No. 325, 28 July 2021, published in the Official Gazette on 3 August 2021, Section 1, pages 19 to 21.
<a href="#">G/TBT/N/BRA/928/Ad d.3</a>	Brazil	<b>Date of Distribution:</b> 09 March 2023  <b>Deadline for Comments:</b> Not Indicated	Medical devices - Addendum	The Draft resolution number 730, 14 October 2019 (previously notified through G/TBT/N/BRA/928), which proposes the updating of the Resolution – RDC number 185, 22 October 2001, which establishes the risk classification, market authorization and technical requirements for labelling and usage instructions of medical devices, was adopted as Resolution - RDC number 751, 15 September 2022.
<a href="#">G/TBT/N/BRA/1466/Ad d.1</a>	Brazil	<b>Date of Distribution:</b> 09 March 2023  <b>Deadline for Comments:</b> Not Indicated	Drug inserts for patients and health professionals - Addendum	The Draft Resolution number 1.137, of 27 December 2022 - previously notified through G/TBT/N/BRA/1466 - which contains provisions on rules for preparing, harmonizing, updating, publishing and making available drug inserts for patients and health professionals, had its period for comments extended by 30 days through Order Number 25, from 6 March 2023.

#### 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)

<a href="#">G/TBT/N/BRA/1467/Add.1</a>	Brazil	<b>Date of Distribution:</b> 09 March 2023  <b>Deadline for Comments:</b> Not Indicated	Medicines - Addendum	<p>The Draft resolution number 1136, 26 December 2022, previously notified through G/TBT/N/BRA/1467 - which regards a proposal to define the general guidelines for the pilot implementation of the optimized analysis procedure, based on risk criteria, to confirm the suitability of the documentation submitted to Anvisa for marketing authorization and post-marketing authorization changes to medicines, had its period for comments extended for 60 days by Order number 27, from 06 March 2023.</p>
<a href="#">G/TBT/N/EGY/261/Add.1</a>	Egypt	<b>Date of Distribution:</b> 08 March 2023  <b>Deadline for Comments:</b> Not Indicated	Manually powered suction equipment intended for oro-pharyngeal suction - Addendum	<p>This addendum concerns the notification of the draft of 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 dated 21 September 2020. Worth mentioning is that this draft standard is technically identical with ISO 10079-3/2022. Producers and importers are kept informed of any amendments in the Egyptian standard through the publication of administrative orders in the official gazette.</p>
<a href="#">G/TBT/N/EGY/262/Add.1</a>	Egypt	<b>Date of Distribution:</b> 08 March 2023  <b>Deadline for Comments:</b> Not Indicated	Medical suction equipment powered from a vacuum or positive pressure gas source generating venturi suction - Addendum	<p>This addendum concerns the notification of the draft of 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</p>

				<p>formerly notified in G/TBT/N/EGY/262 dated 21 September 2020.</p> <p>Worth mentioning is that this draft standard is technically identical with ISO 10079-3/2022.</p> <p>Producers and importers are kept informed of any amendments in the Egyptian standard through the publication of administrative orders in the official gazette.</p>
<a href="#">G/TBT/N/EGY/346</a>	Egypt	<p><b>Date of Distribution:</b> 08 March 2023</p> <p><b>Deadline for Comments:</b> 06 May 2023</p>	Medical suction equipment	<p>This Draft standard specifies general requirements for medical suction equipment that are common to all parts of the ES 6134 series.</p> <p>This document is not applicable to the following:</p> <ul style="list-style-type: none"> <li>a) end-pieces such as suction catheters, drains, curettes, Yankauer suckers and suction tips;</li> <li>b) syringes;</li> <li>c) dental suction equipment;</li> <li>d) anaesthetic gas scavenging systems;</li> <li>e) laboratory suction;</li> <li>f) autotransfusion systems;</li> <li>g) mucus extractors including neonatal mucus extractors;</li> <li>h) suction equipment where the collection container is downstream of the vacuum pump;</li> <li>i) ventouse (obstetric) equipment;</li> <li>j) suction equipment marked for endoscopic use only; and</li> <li>k) plume evacuation systems.</li> </ul> <p>Worth mentioning is that this Draft standard is technically identical with ISO 10079-4/2021.</p>
<a href="#">G/TBT/N/EGY/347</a>	Egypt	<p><b>Date of Distribution:</b> 08 March 2023</p>	Medical suction equipment : electrically powered suction equipment	<p>This Draft standard specifies safety and performance requirements for electrically powered medical and surgical suction equipment. It applies to equipment used in health care</p>

		<b>Deadline for Comments:</b> 06 May 2023		facilities such as hospitals, for domiciliary care of patients and for field use and transport use. Worth mentioning is that this Draft standard is technically identical with ISO 10079-1/2022.
<a href="#">G/TBT/N/E GY/348</a>	Egypt	<b>Date of Distribution:</b> 08 March 2023  <b>Deadline for Comments:</b> 06 May 2023	Medical electrical equipment : infant transport incubator equipment	This Draft standard applies to the basic safety and essential performance of infant transport incubator equipment, as defined in.3.208, also referred to as equipment. If a clause or sub clause is specifically intended to be applicable to equipment only, or to systems only, the title and content of that clause or sub clause will say so. If that is not the case, the clause or sub clause applies both to equipment and to systems, as relevant. Hazards inherent in the intended physiological function of equipment or systems within the scope of this document are not covered by specific requirements in this document. Worth mentioning is that this Draft standard is technically identical with IEC 60601-2-20:2020
<a href="#">G/TBT/N/E GY/349</a>	Egypt	<b>Date of Distribution:</b> 08 March 2023  <b>Deadline for Comments:</b> 06 May 2023	Medical electrical equipment : infant incubators	This Draft standard applies to the basic safety and essential performance of infant incubators, as defined in.3.209, also referred to as equipment. If a clause or sub clause is specifically intended to be applicable to equipment only, or to systems only, the title and content of that clause or sub clause will say so. If that is not the case, the clause or sub clause applies both to equipment and to systems, as relevant. Hazards inherent in the intended physiological function

				of equipment or systems within the scope of this document are not covered by specific requirements in this document. Worth mentioning is that this Draft standard is technically identical with IEC 60601-2-19:2020
<a href="#">G/TBT/N/PER/143/Ad d.1</a>	Peru	<b>Date of Distribution:</b> 07 March 2023  <b>Deadline for Comments:</b> Not Indicated	Medicinal and therapeutic use of cannabis and its derivatives - Addendum	Under Supreme Decree No. 004-2023-SA, the Regulations on the medicinal and therapeutic use of cannabis and its derivatives, the draft version of which was notified in document G/TBT/N/PER/145, were approved. The Regulations will enter into force six (6) months after publication in Official Journal, El Peruano. In addition, Article 1 of Supreme Decree No. 005-2019-SA, approving the Regulations in Law No. 30681 regulating the medicinal and therapeutic use of cannabis and its derivatives, was repealed.
<a href="#">G/TBT/N/PHL/289/Ad d.2</a>	Philippines	<b>Date of Distribution:</b> 06 March 2023  <b>Deadline for Comments:</b> Not Indicated	Investigational products used in clinical trials - Addendum	Guidelines on Regulatory Reliance on the Conduct of Clinical Trials

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](mailto:BPS@dti.gov.ph) copy [bps.smd@dti.gov.ph](mailto:bps.smd@dti.gov.ph).

Thank you.

Sincerely,

**NEIL P. CATAJAY**   
Director