

07 December 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 25 November to 01 December 2023.

Relative thereto, we respectfully invite stakeholders to comment on the six (6) notified draft technical regulations from three (3) WTO Members:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
<a href="#">G/TBT/N/BRA/1283/A</a> <a href="#">dd.1</a>	Brazil	<b>Date of Distribution:</b> 28 November 2023  <b>Deadline for Comments:</b> Not Indicated	Low-risk medicines subject to notification - Addendum	The Normative Instruction number 106, 12 November 2021 - previously notified through G/TBT/N/BRA/1283 - which establishes the list of low-risk medicines subject to notification, was changed by the Normative Instruction - IN number 265, 23 November 2023.
<a href="#">G/TBT/N/BRA/1485/A</a> <a href="#">dd.2</a>	Brazil	<b>Date of Distribution:</b> 01 December 2023  <b>Deadline for Comments:</b> Not Indicated	Surgical gloves and gloves for non-surgical procedures - Addendum	The Draft Resolution number 1161, 18 May 2023 - previously notified through G/TBT/N/BRA/1485 - which establishes the minimum identity and quality requirements for surgical gloves and gloves for non surgical procedures made of natural rubber, synthetic rubber, mixture of natural and synthetic rubbers and polyvinyl chloride, under a health surveillance regime, was adopted as Resolution - RDC number 825, October 26th, 2023.
<a href="#">G/TBT/N/BRA/1509</a>	Brazil	<b>Date of Distribution:</b> 01 December 2023  <b>Deadline for Comments:</b> 02 February 2024	Pharmaceutical products	This Draft Resolution is regarded to rules for establishing nomenclatures and updating the list of Brazilian Common Denominations (DCB).
<a href="#">G/TBT/N/KEN/1152/A</a> <a href="#">dd.1</a>	Kenya	<b>Date of Distribution:</b> 27 November 2023  <b>Deadline for Comments:</b>	Cotton ear bud - Addendum	Kenya would like to inform WTO Members that the East African Standard EAS 1069:2021 Cotton ear bud — Specification; notified in G/TBT/N/KEN/1152 as DEAS 1069: 2021 was adopted as a Kenya Standard KS EAS 1069: 2022 on 29th

### 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)

		Not Indicated		September 2023 via gazette notice No. 13353 dated 29th September 2023.
<a href="#">G/TBT/N/KEN/1153/Add.1</a>	Kenya	<b>Date of Distribution:</b> 27 November 2023  <b>Deadline for Comments:</b> Not Indicated	Medical cotton swab - Addendum	Kenya would like to inform WTO Members that the East African Standard EAS 1070:2021 Medical cotton swab — Specification; notified in G/TBT/N/KEN/1153 as DEAS 1070:2021 was adopted as a Kenya Standard KS EAS 1070: 2022 on 29th September 2023 via gazette notice No. 13353 dated 29th September 2023.
<a href="#">G/TBT/N/USA/2071</a>	United States	<b>Date of Distribution:</b> 01 December 2023  <b>Deadline for Comments:</b> 28 February 2024	Wound dressings and liquid wound washes containing antimicrobials and/or other chemicals	The Food and Drug Administration (FDA, Agency, or we) are proposing to classify certain types of wound dressings and liquid wound washes containing antimicrobials and/or other chemicals (unclassified, preamendments devices) as solid wound dressings; wound dressings formulated as a gel, cream, or ointment; and liquid wound washes. FDA currently regulates these unclassified devices as devices requiring premarket notification (510(k) requirements), with the product codes FRO, GER, MGP, MGQ, and EFQ, but FDA intends to create new product codes for these proposed classifications upon finalization of this classification action. FDA is proposing to classify certain wound dressings and liquid wound washes containing antimicrobials with a high level of antimicrobial resistance (AMR) concern (i.e., medically important antimicrobials) into class III. In addition, FDA is proposing to classify certain wound dressings and liquid wound washes containing antimicrobials with a medium or low level of AMR concern and/or other chemicals, into class II (subject to special controls and 510(k) requirements).

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

