

23 January 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 07 to 13 January 2023.

Relative thereto, we respectfully invite stakeholders to comment on the three (3) notified draft technical regulations from European Union, Republic of Korea, and Peru:

| Document Symbol | Notifying Member | Relevant Dates | Products Covered | Summary |
|-----------------------------------|-------------------|---------------------------------------------------------------------------------------------------------|---------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| G/TBT/N/EU/943 | European Union | Date of Distribution: 09 January 2023 Deadline for Comments: 18 January 2023 | 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/KO/R/1125 | Republic of Korea | Date of Distribution: 12 January 2023 Deadline for Comments: 12 March 2023 | Medical devices | The proposed amendment to the Standards of Medical Device Good Manufacturing Practices is as follows: 1) Re-classification of medical device product group 2) Modification of required dossier for documentation review 3) Complete transfer of KGMP audit authority to Korean private conformity assessment bodies for export-only medical devices 4) Clarification of combination medical devices that are subject to KGMP audit |

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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)

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| | | | | 5) Clarification of the KGMP audit procedure |
| G/TBT/N/PER/138/Add.1 | Peru | Date of Distribution: 13 January 2023 Deadline for Comments: Not Indicated | Ophthalmic instruments : impression and applanation tonometers - Addendum | Through Directorial Resolution No. 014-2022/INACAL/DM, published in the Diario Oficial "El Peruano" of May 5, 2022, the "Peruvian Metrological Standard" is approved NMP 025:2022 Ophthalmic Instruments - Impression and Applanation Tonometers, 1st edition", mandatory, which consists of the following parts: Part 1: Technical and metrological requirements. Part 2: Test procedures. Part 3: Test report format. It enters into force within one (1) year from its publication in the Official Gazette. |

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