

22 February 2022

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.tbtime.wto.org) from 05 to 11 February 2022.

Relative thereto, we respectfully invite stakeholders to comment on the one (4) notified draft technical regulations from three (3) WTO Member Countries:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/ECU/511	Ecuador	Date of Distribution: 10 February 2022 Deadline for Comments: 05 March 2022	Products for human use and consumption	Draft Technical Health Regulations for the approval of clinical trials and the certification of products for human use and consumption and their establishments, during health emergencies or emergency situations, national or international
G/TBT/N/EU/873	European Union	Date of Distribution: 11 February 2022 Deadline for Comments: 06 March 2022	Certain class D in vitro diagnostic medical devices	Draft Commission Implementing Regulation laying down common specifications for certain class D in vitro diagnostic medical devices in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council
G/TBT/N/PHL/281	Philippines	Date of Distribution: 11 February 2022 Deadline for Comments: 06 March 2022	Medical device	Adoption of the Post-Marketing Alert System (PMAS) Requirements, Annex 5 of the ASEAN Medical Device Directive (AMDD)
G/TBT/N/PHL/280	Philippines	Date of Distribution: 11 February	In-vitro diagnostic medical devices	Draft FDA Circular entitled "Specific List of Registrable In Vitro Diagnostic Medical

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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)

		2022 Deadline for Comments: 06 March 2022		Devices (IVDs) and Revised Technical Requirements for Registration of COVID-19 Test Kits"
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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 Mrs. Catherine Antonio-Paguinto (CatherineAntonio@dti.gov.ph) and Ms. Jasmin E. Metre (JasminMetre@dti.gov.ph).

Thank you.

Sincerely,

NEIL P. CATAJAY 
Director