

01 July 2026

NOTICE TO STAKEHOLDERS

Please be notified that the following international standards on **Biological and clinical evaluation of medical devices** published by the International Organization for Standardization (ISO) are intended/recommended for adoption as Philippine National Standards (PNS):

1. ISO 10993-1:2025 - Biological evaluation of medical devices — Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process
2. ISO 10993-6:2026 - Biological evaluation of medical devices — Part 6: Tests for local effects after implantation
3. ISO 10993-7:2026 - Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals
4. ISO 10993-10:2021 - Biological evaluation of medical devices — Part 10: Tests for skin sensitization
5. ISO 10993-17:2023/Amd 1:2025 - Biological evaluation of medical devices — Part 17: Toxicological risk assessment of medical device constituents with Amendment 1
6. ISO 14155:2026 - Clinical investigation of medical devices for human subjects — Good clinical practice

The adoption of international standards as Philippine National Standards (PNS) is in line with good standardization practice and is consistent with the Philippines' commitment to the World Trade Organization Technical Barriers to Trade (WTO-TBT) agreement. Likewise, this will facilitate immediate access to international standards by the local companies, industries, academe, consumers, testing/research institutions, professional associations and other stakeholders.

Please be informed that stakeholders may access the read-only copy of the standards and submit their comments through their 1BPS portal account at standardsph.dti.gov.ph.

BUREAU OF PHILIPPINE STANDARDS

Alternatively, you may accomplish the attached Access Request Form to request access to the documents. Comments, inputs or other concerns regarding the intent or recommendation to adopt the standards may be submitted using the attached commenting template and sent via email to bps.sdd@dti.gov.ph on or before **08 September 2026**. We would appreciate if you could also share this information with other stakeholders within your purview.

Finally, please be advised that official copies of promulgated Philippine National Standards (PNS) are available at the BPS Standards Data Center with contact details below:

BPS Standards Data Center
3rd Floor, Trade and Industry Building
361 Sen. Gil Puyat Ave., Makati City
Email: bps@dti.gov.ph; standardsdatacenterbps@dti.gov.ph

Thank you.

Sincerely,

NEIL P. CATAJAY
Director

Att.: A/s
Ref: *SDD10_26NOA#11*