



THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF INDUSTRY AND TRADE
TANZANIA BUREAU OF STANDARDS (TBS)



ISO 9001:2015 Certified

Member of the International Standardization (ISO), Codex Alimentarius Commission (WHO/FAO), Agent for ISO and other National Standards Bodies

In reply please quote:

Ref. No.: TBS/DSD/SD/CDC/A-3/VOL.II/86

Date: 2026- 02 - 24

To: All Medical Devices Stakeholders and
All interested parties.

RE: DRAFT TANZANIA STANDARDS FOR STAKEHOLDER'S COMMENTS.

Please refer to the heading above.

2. Tanzania Bureau of Standards (TBS) is in the process of developing standards on;

- i. TBS/CDC 21(4201) DTZS/ISO 6009:2016(confirmed 2021) Hypodermic needles for single use - Colour coding for identification
- ii. TBS/CDC 21(4287) DTZS/ISO 16408:2025 Dentistry — Oral care products — Oral rinses
- iii. TBS/CDC 21(4288) DTZS/ISO 28158:2018(confirmed 2024) Dentistry – Integrated dental floss and handles
- iv. TBS/CDC 21(4208) DTZS/ISO 20126:2022 Dentistry — Manual toothbrushes — General requirements and test methods
- v. TBS/CDC 21(4202) DTZS/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
- vi. TBS/CDC 21(4205) DTZS/ISO 10993-4:2017(Confirmed 2023) Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
- vii. TBS/CDC 21(4206) DTZS/ISO 10993-17:2023 Biological evaluation of medical devices Part 17: Toxicological risk assessment of medical device constituents
- viii. TBS/CDC 21(4207) DTZS/ISO 10993-18:2020(Confirmed 2025) Biological evaluation of medical devices Part 18: Chemical characterization of medical device materials within a risk management process

3. According to procedures for development of Tanzania Standard(s), the Draft Standards are hereby circulated for stakeholders' comments.

TBS HEADQUARTERS

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All Correspondence should be addressed to the **DIRECTOR GENERAL**

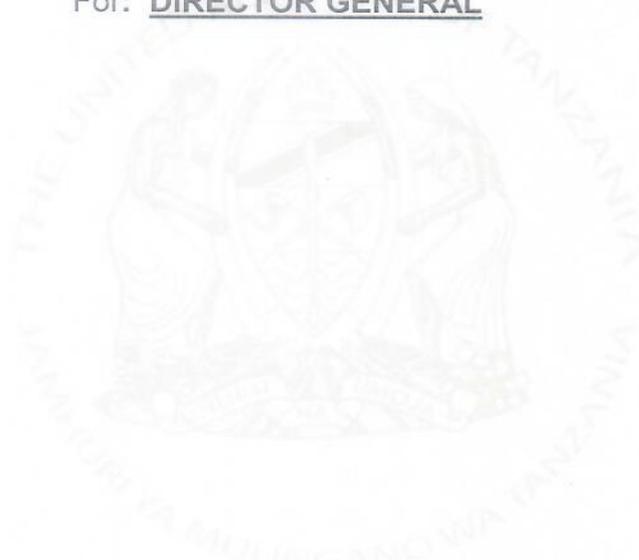
4. Being one of the key stakeholders in standards development, your kindly requested to go through the above draft standards and send your comments regarding its technical contents. Suggestion which entails revision of text should indicate the preferred wording and the relevant clause against each comment.
5. Among the circulated Draft Standards are international standards proposed for identical adoption; therefore, the complete contents of those standards may be obtained from TBS Library.
6. Your comments can be submitted in electronic form or hard copy as per the attached form and we will appreciate receiving your comments before **30th April 2026**.

Thanking you in advance for your continued cooperation.



Alexander Mashalla
For: **DIRECTOR GENERAL**

Attach;



"Inspiring Quality and Safety for Better Livelihood"

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