



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

To all Medical Devices Stakeholders,  
All interested parties.

Dear Sir/Madam;

**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 standard on;
  - i. CDC 21 (474) DTZS/ISO 11135:2014 Sterilization of Healthcare Products-Ethylene Oxide-Part 1: Requirements, Validation and routine control of a sterilization process for medical devices.
  - ii. CDC 21 (476) DTZS/ISO 7199:2016 Cardiovascular implants and artificial organs - Blood-Gas exchangers (Oxygenators).
  - iii. CDC 21 (477) DTZS/ISO 14708-1:2014 Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer.
  - iv. CDC 21 (478) DTZS/ISO 14708-2:2019 Implants for surgery - Active implantable medical devices - Part 2: Cardiac pacemakers.
3. According to procedures for preparation of Tanzania Standards, these draft standards on Medical Devices are hereby circulated for stakeholders' comments. Being one of the key stakeholders of the sector in standards development, we kindly request you to go through the 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 should be quoted against each comment.
4. In case you find it suitable and no comments, please notify accordingly.
5. Your comments can be submitted in electronic form or hard copy as per attached form.
6. We will appreciate receiving your comments before **2021-03-07**.

Yours Sincerely,

Alexander Mashalla  
For: **DIRECTOR GENERAL**

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