



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/CDC/A-3/VOL. II/25**

Date: **2021-12-15**

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 (941) DTZS/ISO11607-1:2019 Packaging for terminally sterilized medical devices-Part 1:Requirements for materials, sterile barrier systems and packaging systems**
- ii. **CDC 21 (939) DTZS/ISO14630:2012 Non-active surgical implants-General requirements**
- iii. **CDC 21 (938) DTZS/ISO 5832-9:2019 Implants for surgery-Metallic materials-Part 9:Wrought high Nitrogen stainless steel**
- iv. **CDC 21 (936) DTZS/ISO14155:2020 Clinical investigation of medical devices for human subjects - Good clinical practice**
- v. **CDC 21 (934) DTZS/ISO15675:2016 Cardiovascular implants and artificial organs-Cardiopulmonary bypass systems-Arterial blood line filter**
- vi. **CDC 21 (932) DTZS/ISO 6892-1:2019 Metallic materials-Tensile testing-Part 1:Method of test at room temperature**
- vii. **CDC 21 (930) DTZS/ISO14971:2019 Medical devices-Application of risk management to medical devices**
- viii. **CDC 21 (929) DTZS/ISO 5832-14:2019 Implants for surgery-Metallic materials-Part 14:Wrought Titanium 15-Molybdenum 5-Zirconium 3-Aluminium alloy**
- ix. **CDC 21 (928) DTZS/ISO 5832-12:2019 Implants for surgery-Metallic materials-Part 12:Wrought-Cobalt-Chromium-Molybdenum alloy**
- x. **CDC 21 (927) DTZS /ISO 5832-11:2014 Implants for surgery-Metallic materials-Part 11:Wrought Titanium 6-Aluminium 7-Niobium alloy**

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

3. According to procedures for preparation of Tanzania Standards, the draft Tanzania standards 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.

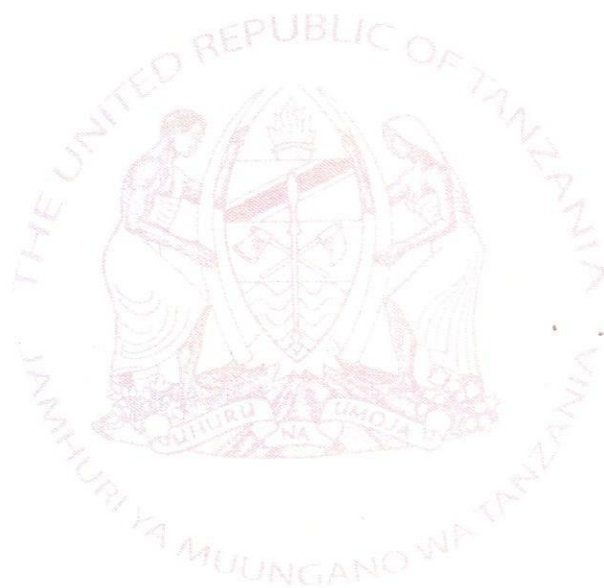
6. We will appreciate receiving your comments before **2022-02-15**.

Yours Sincerely,



Alexander Mashalla

For: **DIRECTOR GENERAL**



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