



2017-03-23

TBS/CDC/A-3/285

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,

Dear Sir/Madam,

RE: DRAFT TANZANIA STANDARDS FOR STAKEHOLDER'S COMMENTS.

Please refer to the heading above;

Tanzania Bureau of Standards (TBS) is in the process of developing Standards on:-

1. **TBS/CDC 21(5149) P3 / ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity**
2. **TBS/CDC 21(5150) P3 / ISO 10993- 4:2002 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood**

According to procedures for preparation of Tanzania Standard(s), the draft Standards are hereby circulated for Stakeholders' comments.

Being one of the key stakeholders in standards development, we kindly request you to go through the draft standard 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. These are international Standards for adoption, for details of requirements you may obtain a copy from Tanzania Bureau of Standards Library in case you find it suitable and if no comments, please notify accordingly.

Your comments can be submitted in electronic form or hard copy as per attached form.

We will appreciate receiving your comments before **2017-05-24**

Thanking you in advance for your kindly and continued cooperation.

Yours Sincerely,

Alexander Mashalla
For: DIRECTOR GENERAL

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