



2016 – 12 – 28 TBS/CDC/A-3/283

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 (5018) P3 / ISO 13485:2016-Medical Devices-Quality management systems-Requirements for regulatory purposes.
2. TBS/CDC 21 (5019) P3 / ISO 10993- 1:2009-Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process.
3. TBS/CDC 21 (5020) P3 / ISO 10993-2:2006- Biological evaluation of medical devices-Part 1: Animal welfare requirements.

According to procedures for preparation of Tanzania Standard(s), the draft standard 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 (s) 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. In case you find it suitable and 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 **2017-02-28**.

Thanking you in advance for your kindly and continued cooperation.

Yours Sincerely,

Nickonia Mwabuka  
For: **DIRECTOR GENERAL**

**Attach.**

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