



TANZANIA BUREAU OF STANDARDS (TBS)
SHIRIKA LA VIWANGO TANZANIA

ISO 9001:2015 Certified

DATE
Tarehe

2020-11-20

REFERENCE
Kumbukumbu

TBS/CDC/A-3/VOL. II 1

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(469) DTZS/ISO 10993-13:2010 Biological evaluation of medical devices -Part 13: Identification of degradation products from polymeric medical devices.
- ii. CDC 21(465) DTZS/ISO 10993-7:2008 Biological evaluation of medical Devices-Part 7: Ethylene oxide sterilization residuals.
- iii. CDC 21(472) DTZS/ISO 7886-3:2020 Sterile hypodermic syringes for single use -Part 3: Auto-disable syringes for fixed dose immunization (**Revision of TZS 993-3:2007**).

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 **2021-01-28**.

Yours Sincerely,

Alexander Mashalla
For: **DIRECTOR GENERAL**

TBS HEADQUARTERS

Physical Address

Junction Morogoro/Sam Nujoma Rds
Ubungu, Dar es Salaam
P.O. Box 9524
DAR ES SALAAM, TANZANIA

Fax: +255 22 2450959

Hotline: 0800 110827

info@tbs.go.tz

www.tbs.go.tz

TBS_Tanzania

tbs Viwango

TBS LAKE ZONE

Physical Address

NSSF Building, 5th Floor
P.O. Box 1814
MWANZA,
TANZANIA
Gen: +255 28 2501127

TBS NORTHERN ZONE

Physical Address

NSSF Mafao House Building,
2nd Floor
P.O. Box 2399
ARUSHA, TANZANIA
Gen: +255 27 2520143

TBS CENTRAL ZONE

Physical Address

PSPF Building, 1st Floor
P.O. Box 2956
DODOMA,
TANZANIA
Gen: +255 26 2320310

TBS SOUTHERN HIGHLANDS ZONE

Physical Address

Regional Livestock Office Building
P.O. Box 1674
MBEYA,
TANZANIA
Gen: +255 25 2502848

TBS SOUTHERN ZONE

Physical Address

MTUWASA Building,
Mtwara
P.O. Box 1396
MTWARA, TANZANIA
Gen: +255 23 2334477