



DRAFT TANZANIA STANDARD

Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood

TANZANIA BUREAU OF STANDARDS

National foreword

The Tanzania Bureau of Standards is the statutory National standards body for Tanzania, established under the Act.No.3 of 1975, amended by Act.No.2 of 2009.

This Draft Tanzania Standard is being adopted by Medical devices Technical Committee under the supervision of the Chemicals Divisional Standards Committee.

This Draft Tanzania Standard is the identical adoption of an International Standard, ISO 10993:2017(Confirmed 2023), *Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood*.

This second edition cancels and replaces the first edition TZS 1968-4: 2017, *Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood*.

Terminology and conventions

Some terminologies and certain conventions are not identical with those used as Tanzania standards; attention is drawn especially to the following: -

The comma has been used as a decimal marker for metric dimensions. In Tanzania Standards, its current practice to use full point on the baseline as the decimal marker.

Where the words “International Standard(s)” appear, referring to this standard they should read “Tanzania Standard”.

Scope

This document specifies general requirements for evaluating the interactions of medical devices with blood. It describes

- a) a classification of medical devices that are intended for use in contact with blood, based on the intended use and duration of contact as defined in ISO 10993-1,
- b) the fundamental principles governing the evaluation of the interaction of devices with blood,
- c) the rationale for structured selection of tests according to specific categories, together with the principles and scientific basis of these tests.

Detailed requirements for testing cannot be specified because of limitations in the knowledge and precision of tests for evaluating interactions of devices with blood. This document describes biological evaluation in general terms and may not necessarily provide sufficient guidance for test methods for a specific device.

The changes in this document do not indicate that testing conducted according to prior versions of this document is invalid. For marketed devices with a history of safe clinical use, additional testing according to this revision is not recommended.