DRAFT TANZANIA STANDARD

Biological evaluation of medical devices Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process

TANZANIA BUREAU OF STANDARDS

Second Edition 2026

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 10993:2025, *Biological evaluation of medical devices Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process.*

This second edition cancels and replaces the first edition TZS 1968-1: 2017, *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*.

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 the requirements and general principles governing the biological evaluation of medical devices within a risk management process according to ISO 14971.
This document applies to the biological evaluation of medical devices that have direct contact or indirect contact with either:
— a patient's body during intended use or reasonably foreseeable misuse; or
— the body of other users who are not patients, if the medical device is intended for personal protection (e.g. medical gloves, surgical masks).

Biological evaluation assesses the biological safety of the medical device by considering the biological risks associated with:
— constituents of a medical device; and
— tissue-device interactions (including physical effects).
The biological evaluation specified in this document can address the biological safety of the medical device, considering the life cycle from design and development through initial use of the finished medical device to final decommissioning or withdrawal from use. The biological evaluation considers both the biological safety of the finished device in first use, and the significance of any changes to the medical device which can occur throughout the life cycle. However, the evaluation of risks related to environmental impacts of decommissioning of medical devices are not within the scope of this document. This document does not mandate re-testing of medical devices that are already on the market and have established and acceptable safety profiles (see 6.6.2).

This document can be useful to support clinical or usability evaluations of medical devices. For example, a biological evaluation is a pre-requisite for conducting a clinical trial. This means that principles outlined in

this document can be applied to the evaluation of prototype or development stage devices, as well as to finished medical devices.

Other parts of the ISO 10993 series cover specific aspects of biological evaluation, such as chemical characterization, biological testing, sample preparation, animal welfare and toxicological risk assessment. For some types of medical devices, specific requirements from other standards (outside the ISO 10993 series) can be considered with a justification for the approach taken if there are differences between the requirements of the ISO 10993 series and those provided in other standards. For example, the ISO 18562 series provides specific requirements for biological evaluation of breathing gas pathway medical devices and ISO 7405 provides specific requirements for biological evaluation of dental devices.

The evaluation of risks related to infectious agents [e.g. bacteria, moulds, yeasts, viruses, transmissible spongiform encephalopathy (TSE) agents] is not within the scope of this document.

NOTE 1 The evaluation of bacterial endotoxins is addressed by ISO 11737-3.

NOTE 2 The evaluation of risks related to viruses, TSE agents and other pathogens originating from materials of animal origin is addressed by the ISO 22442 series.