DRAFT TANZANIA STANDARD

Biological evaluation of medical devices Part 18: Chemical characterization of medical device materials 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 10993-18:2020(Confirmed 2025), *Biological evaluation of medical devices Part 18: Chemical characterization of medical device materials within a risk management process.*

This second edition cancels and replaces the first edition TZS 1968-18: 2019, *Biological evaluation of medical devices Part 18: Chemical characterization of medical device materials 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 a framework for the identification, and if necessary, quantification of constituents of a medical device, allowing the identification of biological hazards and the estimation and control of biological risks from material constituents, using a generally stepwise approach to the chemical characterization which can include one or more of the following:

— the identification of its materials of construction (medical device configuration);
— the characterization of the materials of construction via the identification and quantification of their chemical constituents (material composition);
— the characterization of the medical device for chemical substances that were introduced during manufacturing (e.g. mould release agents, process contaminants, sterilization residues);
— the estimation (using laboratory extraction conditions) of the potential of the medical device, or its materials of construction, to release chemical substances under clinical use conditions (extractables);
— the measurement of chemical substances released from a medical device under its clinical conditions of use (leachables).

This document can also be used for chemical characterization (e.g. the identification and/or quantification) of degradation products. Information on other aspects of degradation assessment are covered in ISO 10993-9, ISO 10993-13, ISO 10993-14 and ISO 10993-15.

The ISO 10993 series is applicable when the material or medical device has direct or indirect body contact (see ISO 10993-1 for categorization by nature of body contact).

This document is intended for suppliers of materials and manufacturers of medical devices, to support a biological evaluation..