



DRAFT TANZANIA STANDARD

**Biological evaluation of medical devices – Part 5: Tests
for *in vitro* cytotoxicity**

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 Hospital Textiles Technical Committee under the supervision of the Textile and Leather Divisional Standards Committee.

This Draft Tanzania Standard is the identical adoption of **ISO 10993-5:2009 Biological evaluation of medical devices —Part 5: Tests for in vitro cytotoxicity**, published by International Organization for Standardization.

The text of the International Standard is hereby recommended for approval without deviation for publication as Draft Tanzania Standard.

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 part of ISO 10993 describes test methods to assess the in vitro cytotoxicity of medical devices. These methods specify the incubation of cultured cells in contact with a device and/or extracts of a device either directly or through diffusion.

These methods are designed to determine the biological response of mammalian cells in vitro using appropriate biological parameter.