



TBS/AFDC 11 (2273) DTZS/ISO 20404:2023

## DRAFT TANZANIA STANDARD

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Biotechnology - Bioprocessing - General requirements for the design of packaging to contain cells for therapeutic use

**TANZANIA BUREAU OF STANDARDS**

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## **NATIONAL FOREWORD**

The Tanzania Bureau of Standards is a 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 prepared by the Biotechnology Technical Committee, under supervision of Agriculture and Food Standards Divisional Committee (AFDC)

This draft Tanzania standard specifies general requirements and considerations for the design of packaging used to contain cells for therapeutic use. It is applicable to packaging intended to contain the final products of cells for therapeutic use, as well as their starting and intermediate materials.

This draft Tanzania standard does not apply to:

- a) receptacles used for processing cells in manufacturing processes, e.g. cell culture flask or bag;
- b) shipping containers containing packages for transport
- c) services that utilize packages, e.g. storage services

This draft Tanzania standard is identical to the ISO 20404:2023 Biotechnology - Bioprocessing - General requirements for the design of packaging to contain cells for therapeutic use, published by International Organization for Standardization.

## **TERMINOLOGY AND CONVENTIONS**

This text of the international standards if found suitable, may be approved for application as a Tanzania Standard without deviations.

Some terminology and certain conventions are not identical with those used in Tanzania standards; attention is drawn especially to the following.

- 1) The comma has been used as a decimal marker for metric dimensions. In Tanzania standards, it is current practice to use a full point on the base line as the decimal marker.
- 2) Wherever the words “International Standard” appear, referring to this Standard they should read as “Tanzania Standard”.