** AFDC 11 (798) DTZS/ ISO 21899:2020**

**DRAFT TANZANIA STANDARD**

Biotechnology - Biobanking - General requirements for the validation and verification of processing methods for biological material in biobanks

**TANZANIA BUREAU OF STANDARDS**

**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 Tanzania Standard is being prepared by the Biotechnology Technical Committee, under supervision of Agriculture and Food Standards Divisional Committee (AFDC)

This Tanzania standard specifies the validation and verification requirements applicable to a biobank to be able to demonstrate that it operates its processing of biological materials with validated and/or verified methods that are fit for purpose.

This Tanzania standard intended for use in the implementation and validation of processing methods for biological materials.

This Tanzania standard covers method validation and verification for the production of all biological materials. This Tanzania standard does not apply to biological material intended for food/feed production, laboratories undertaking food/feed analysis, and/or therapeutic use.

This Tanzania standard is identical to the ISO 21899:2020 Biotechnology - Biobanking - General requirements for the validation and verification of processing methods for biological material in biobanks 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.

1. Wherever the words “International Standard” appear, referring to

this Standard they should read as “Tanzania Standard”.