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DRAFT ZANZIBAR NATIONAL STANDARD

Medical devices — Surgical gowns, drapes and clean air suits — Part 1: General requirements

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ZANZIBAR BUREAU OF STANDARDS

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First edition

National Foreword

Zanzibar Bureau of Standards (ZBS) is in the process of adopting the African Standard, ARS 1695-1:2021, Medical devices — Surgical gowns, drapes and clean air suits — Part 1: General requirements and levels, under the Textiles and Leather Products Technical Committee. In accordance with ZBS general procedures, this draft standard is presented to the public in order to receive any technical comment concerns.

Technical Committee Representatives

This Draft Zanzibar National Standard was prepared by the Textiles and Leather Products Standards Technical Committee which consists of representatives from the following organizations:

Chief Government Chemist Laboratory Agency (CGCLA)
College of Engineering and Technology (CoET)
Lumumba Regional Hospital
Special Department Industrial Unit (SPEDIU)
The State University of Zanzibar (SUZA)
Zanzibar National Chamber of Commerce (ZNCC)
Zanzibar Food and Drug Agency (ZFDA)
Zanzibar Fisheries and Marine Resources Research Institute (ZAFIRI)
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1 Scope

This part of Draft Zanzibar National Standard specifies performance requirements for single and multiple use surgical drapes, gowns and clean air suits intended for use in healthcare facilities.

This Draft Zanzibar National Standard specifies information to be supplied to users and third-party verifiers, in addition to the usual labelling of medical devices as stipulated in ISO 15223-1, concerning manufacturing and processing requirements. This standard gives general guidance on the characteristics of single-use and reusable surgical gowns, surgical drapes and clean air suits used as medical devices for patients, clinical staff and equipment. It is intended to prevent the transmission of infective agents between patients and clinical staff during surgical and other invasive procedures. This standard does not include the requirements for incision drapes.

This Draft Zanzibar National Standard does not cover requirements for flammability of products used in laser surgery. Suitable test methods for flammability and resistance to penetration by laser

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radiation, together with an appropriate classification system, are given in ISO 11810.

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