KENYA STANDARD

KS ISO 11193-1:2008 Amd 1:2012

ICS 11.140; 83.140.99

First Edition

APPROVED 2020-04-08

Single-use medical examination gloves

Part 1: Specification for gloves made from rubber latex or rubber solution

AMENDMENT 1

KS ISO 11193-1:2008 Amd 1:2012

TECHNICAL COMMITTEE REPRESENTATION

The following organizations were represented on the Technical Committee:

☐Alpha Medical Manufacturers Ltd.

Association of Medical Engineers of Kenya (AMEK)

Christian Health Association of Kenya (CHAK)

Diverse Management Consultants Ltd.

Equra Health Kenya

Getrudes Children Hospital

Hydromatics Ltd.

Jad's Diagnostics EA Ltd.

Kenya Accreditation Service (KENAS)

Kenya Association of Physicians

Kenya Medical Supplies Agency (KEMSA)

Kenya National Chamber of Commerce and Industry

Medtronic

Ministry of Health

MP Shah Hospital

Roche Diagnostics

Stratus Medical Imaging Solutions Ltd.

Sub-County Health Services, Kamukunji

Kenya Bureau of Standards — Secretariat

REVISION OF KENYA STANDARDS

In order to keep abreast of progress in industry, Kenya Standards shall be regularly reviewed. Suggestions for improvements to published standards, addressed to the Managing Director, Kenya Bureau of Standards, are welcome.

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NATIONAL FOREWORD

This Kenya Standard was prepared by the Medical Devices, Instruments and Hospital Equipment Technical Committee under the guidance of the Standards Projects Committee, and it is in accordance with the procedures of the Kenya Bureau of Standards

This standard is identical with and has been reproduced from ISO 11193-1, Single-use medical examination gloves — Part 1: Specification for gloves made from rubber latex or rubber solution AMENDMENT 1, published by the International Organization for Standardization (ISO). The National Standards Council has endorsed the adoption of the 2012 edition of this amendment as a Kenya Standard.

For the purposes of this standard, the ISO text should be modified as follows:

a) Terminology

The words 'this Kenya Standard' should replace the words 'this ISO Standard' whenever they appear.

b) References

The references to ISO should be replaced by references to the appropriate Kenya Standards, where they have been declared.

INTERNATIONAL STANDARD

ISO 11193-1

> Second edition 2008-09-01 **AMENDMENT 1** 2012-06-15

Single-use medical examination gloves —

Part 1:

Specification for gloves made from rubber latex or rubber solution

AMENDMENT 1

Gants en caoutchouc pour examen, non réutilisables —

Partie 1: Spécifications pour gants fabriqués à partir de latex de caoutchouc ou d'une solution de caoutchouc

AMENDEMENT 1





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Published in Switzerland

Foreword

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The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

Amendment 1 to ISO 11193-1:2008 was prepared by Technical Committee ISO/TC 45, *Rubber and rubber products*, Subcommittee SC 4, *Products (other than hoses)*.

Single-use medical examination gloves —

Part 1:

Specification for gloves made from rubber latex or rubber solution

AMENDMENT 1

Page 6, Subclause 6.3.3

Add the following paragraph after Table 3:

Testing shall be conducted within two months of the date of receipt by the purchaser of the gloves. For gloves that are older than 3 months from the date of manufacture or for which the date of manufacture is not known, the tensile properties need only conform to the "after accelerated ageing" values in Table 3.

Page 6, Table 3

In the last column of the table (Type 2 glove), change the value of the minimum force at break after accelerated ageing from 7,0 N to 6,0 N.

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Price based on 1 page