INTERNATIONAL STANDARD

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Third edition
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Single-use medical examination gloves —

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

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

Reference number
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 45, *Rubber and rubber products*, Subcommittee SC 4, *Products (other than hoses)*.

This third edition cancels and replaces the second edition (ISO 11193-1:2008), which has been technically revised. It also partially incorporates the Amendment ISO 11193-1:2008/Amd:2012.

The main changes compared to the previous edition are as follows:

— some general and editorial changes have been made in 4.1, 4.3, and Clause 5;

— the measurement of length has been corrected from the *second finger* to *middle finger* in 7.1, paragraph 2;

— the NOTE has been changed to main text in 7.3.3;

— the value has been corrected in Table 3;

— some general and editorial changes have been made to Annex A;

— the limit of powdered gloves has been included;

— Figures 1 and 2 of the previous edition have been replaced with Figure 1:

— updates have been made to the powdered surface and powder-free surface;

— the statement on aging gloves over six months old has been updated.

A list of all parts in the ISO 11193 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Single-use medical examination gloves —

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

WARNING — Persons using this document should be familiar with normal laboratory practices. This document does not purport to address all of the safety problems, if any, associated with its use. It is the responsibility of the user to establish appropriate safety and health practices and to ensure compliance with any regulatory conditions.

1 Scope

This document specifies requirements for packaged sterile, or bulked non-sterile, rubber gloves intended for use in medical examinations and diagnostic or therapeutic procedures to protect the patient and the user from cross-contamination. It also covers rubber gloves intended for use in handling contaminated medical materials and gloves with smooth surfaces or with textured surfaces over all or part of the glove.

This document is intended as a reference for the performance and safety of rubber examination gloves. It does not cover the safe and proper usage of examination gloves and sterilization procedures with subsequent handling, packaging and storage procedures.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 37, *Rubber, vulcanized or thermoplastic — Determination of tensile stress-strain properties*

ISO 188, *Rubber, vulcanized or thermoplastic — Accelerated ageing and heat resistance tests*

ISO 2859-1, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

ISO 10993 (all parts), *— Biological evaluation of medical devices*

ISO 23529, *Rubber — General procedures for preparing and conditioning test pieces for physical test methods*

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

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