INTERNATIONAL STANDARD

ISO 10282

Third edition
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Single-use sterile rubber surgical gloves — Specification

Gants en caoutchouc à usage chirurgical, stériles, non réutilisables — Spécifications

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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 45, *Rubber and rubber products*, Subcommittee SC 4, *Products (other than hoses)*.

This third edition cancels and replaces the second edition (ISO 10282:2002), of which it constitutes a minor revision. It also incorporates the Technical Corrigendum ISO 10282:2002/Cor.1:2005 and the following changes:

— addition of isoprene rubber latex as material for type 2 glove;

— only two finishes remain for classification, whereby powdered or powder-free finishes were deleted and introduced in the note;

— addition on the applicability of the warning note to the unit package on the removal of surface-dusting material prior to undertaking operative procedures.

Single-use sterile rubber surgical gloves — Specification

1 Scope

This International Standard specifies requirements for packaged sterile rubber gloves intended for use in surgical procedures to protect the patient and the user from cross-contamination. It is applicable to single-use gloves that are worn once and then discarded. It does not apply to examination or procedure gloves. It covers gloves with smooth surfaces and gloves with textured surfaces over part or the whole glove.

This International Standard is intended as a reference for the performance and safety of rubber surgical gloves. The safe and proper usage of surgical gloves and sterilization procedures with subsequent handling, packaging, and storage procedures are outside the scope of this International Standard.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 15223, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

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

3 Classification

3.1 General

Gloves are classified by type, design, and finish, as given in 3.2 to 3.4.

3.2 Type

Two types are classified:

a) Type 1: gloves made primarily from natural rubber latex.

b) Type 2: gloves made primarily from nitrile rubber latex, isoprene rubber latex, polychloroprene rubber latex, styrene-butadiene rubber solution, styrene-butadiene rubber emulsion or thermoplastic elastomer solution.