## INTERNATIONAL STANDARD



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# Single-use sterile rubber surgical gloves — Specification

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



Reference number ISO 10282:2002(E)

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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 25 % of the member bodies casting a vote.

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

ISO 10282 was prepared by Technical Commute ISO/TC 45, *Rubber and rubber products*, Subcommittee SC 4, *Products* (other than hoses).

This second edition cancels and replaces the first edition (ISO 10282:1994), which has been technically revised.

Annex A forms a normative part of this International Standard.

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## 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 all of the glove.

This 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 the International Standard.

## 2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recenceditions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standard

ISO 37:1994, Rubber, vulcanized or thermoplastic — Determination of tensile stress-strain properties

ISO 188:1998, Rubber, vulcanized or thermoplastic — Accelerated ageing and heat resistance tests

ISO 2859-1:1999, Sampling procedures for inspection by attribute Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

ISO 4648:1991, Rubber, vulcanized or thermoplastic — Determination of comensions of test pieces and products for test purposes

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

ISO 15223:2000, Medical devices — Symbols to be used with medical device labers labelling and information to be supplied

#### 3 Classification

#### 3.1 General

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