INTERNATIONAL STANDARD

ISO 10282

Fourth edition
2023-02

Single-use sterile rubber surgical gloves — Specification

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

Reference number
ISO 10282:2023(E)

© ISO 2023



COPYRIGHT PROTECTED DOCUMENT

© ISO 2023

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

© ISO 2023 – All rights reserved

Contents

Page

Foreword ... **iv**

1 Scope ... **1**

2 Normative references ... **1**

3 Terms and definitions ... **1**

4 Classification ... **2**
4.1 General ... 2
4.2 Material ... 3
4.3 Design ... 3
4.4 Finish ... 3

5 Materials ... **3**

6 Sampling and selection of test pieces ... **4**
6.1 Sampling ... 4
6.2 Selection of test pieces ... 4

7 Requirements ... **4**
7.1 Dimensions ... 4
7.2 Watertightness ... 5
7.3 Tensile properties ... 5
7.3.1 General ... 5
7.3.2 Force at break and elongation at break before accelerated ageing ... 5
7.3.3 Force at break and elongation at break after accelerated ageing ... 5
7.3.4 Force required to produce 300 % elongation ... 6
7.4 Sterility ... 6

8 Packaging ... **6**

9 Marking ... **6**
9.1 General ... 6
9.2 Inner package ... 6
9.3 Unit package ... 6
9.4 Multi-unit package ... 7

Annex A (normative) **Measurement of dimensions (width, length and thickness)** ... **8**

Annex B (normative) **Test method for watertightness** ... **9**

Bibliography ... **11**

© ISO 2023 – All rights reserved

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 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 fourth edition cancels and replaces the third edition (ISO 10282:2014), which has been technically revised.

The main changes are as follows:

— the previous Figures 1 and 2 have been replaced with Figure A.1;

— the powdered surface and powder-free surface have been updated;

— a statement on ageing gloves over six months old has been added;

— a new Annex A has been added and the previous Annex A has renamed to Annex B.

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.

© ISO 2023 – All rights reserved

Single-use sterile rubber surgical gloves — Specification

1 Scope

This document specifies requirements for packaged sterile rubber gloves intended for use in surgical procedures to protect the patient and the user from cross-contamination.

This document is applicable to single-use gloves that are worn once and then discarded. It does not apply to examination or procedure gloves.

This document covers gloves with smooth surfaces and gloves with textured surfaces over part or the whole glove.

This document is intended to be 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 document.

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

For the purposes of this document, the following terms and definitions apply.

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

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

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

3.1
powdered glove
glove where a powder has been added as a part of the manufacturing process, generally to facilitate donning

© ISO 2023 – All rights reserved

3.2
powder-free glove
glove which has been manufactured without the deliberate addition of powdered materials to facilitate donning

Note 1 to entry: Powder-free is also referred to as “powderless”, “no powder” or “non-powdered” or other words to that effect.

3.3
lot
definite amount of some product, material or service, collected together

Note 1 to entry: An inspection lot may consist of several batches or parts of batches.

[SOURCE: ISO 2859-1:1999, 3.1.13]

3.4
lot size
number of items in a lot

[SOURCE: ISO 2859-1:1999, 3.1.14]

3.5
inspection level
index of the relative amount of inspection of an acceptance sampling scheme, chosen in advance, and relating the sample size to the lot size

[SOURCE: ISO 3534-2:2006, 4.3.5, modified — Notes 1 and 2 to entry have been deleted.]

3.6
acceptance quality limit
AQL
quality level that is the worst tolerable process average when a continuing series of lots is submitted for acceptance sampling

[SOURCE: ISO 2859-1:1999, 3.1.26, modified — Notes 1 and 2 to entry have been deleted.]

3.7
force at break
tensile stress recorded at the moment of rupture

[SOURCE: ISO 37:2017, 3.4, modified — the term has been modified from "tensile strength at break".]

3.8
elongation at break
tensile strain in the test length at breaking point

[SOURCE: ISO 37:2017, 3.5, modified — the symbol "E_b" and Note 1 to entry have been deleted.]

3.9
force at a given elongation
tensile stress in the test length required to produce a given elongation

[SOURCE: ISO 37:2017, 3.7, modified — "stress" has been changed to "force" in the term, and "S_e" and Note 1 to entry have been deleted.]

4 Classification

4.1 General

Gloves are classified by material, design and finish, as given in 4.2 to 4.4.

© ISO 2023 – All rights reserved