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Single-use rubber gloves for general applications — Specification

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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 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. (standards.iteh.ai)

This document was prepared by Technical Committee ISO/TC 45, *Rubber and rubber products*, Subcommittee SC 4, *Products (other than hoses)*. ISO 25518:2021 https://standards.iteh.ai/catalog/standards/sist/4cde675c-5de1-4ae7-926d-

This second edition cancels and replaces the first edition (ISO 25518:2009), which has been technically revised.

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

- Figure 1 in 4.2 has been changed;
- value of powder content limit has been added in <u>6.2</u>.

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 <u>www.iso.org/members.html</u>.

Single-use rubber gloves for general applications — Specification

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 the physical requirements and sampling and testing methods for single-use rubber gloves, made from natural rubber latex, synthetic rubber latex or rubber solution, intended for general applications, but not gloves intended for medical purposes.

It does not cover the safe and proper usage of the gloves.

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 25 Accelerated ageing and heat resistance tests https://standards.iteh.ai/catalog/standards/sist/4cde675c-5de1-4ae7-926d-

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

3 Terms and definitions

No terms and definitions are listed in this document.

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 <u>https://www.electropedia.org/</u>

4 Requirements

4.1 Materials

Gloves shall be manufactured from suitable materials. Any pigment, surface treatment, lubricant or powder used shall be non-toxic and shall be disclosed on request. Substances used for the treatment that could be transferred to the skin during use shall not cause any harm.

4.2 Dimensions

When measured at the points shown in Figure 1, gloves shall comply with the dimensions for length (*L*) and palm width (*W*) given in Table 1, using the inspection level and acceptance quality limits (AQL) given in Table 3.

The measurement of length (*L*) shall be the shortest distance between the tip of the middle finger and the cuff end.

The length (*L*) measurement may be taken by hanging the glove on a suitable mandrel with a tip radius of 5 mm.

The measurement of width (W) shall be at the midpoint between the base of the index finger and the base of the thumb to the opposite end of the glove. The width (W) measurement shall be made with the glove placed on a flat surface.



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L length W width

Figure 1 — Measurement points for the length and width of the glove

Size	Width	Minimum length	
	(dimension W in <u>Figure 1</u>) mm	(dimension <i>L</i> in Figure 1) mm	
Extra small (XS)	≤ 80	220	
Small (S)	80 ± 10	220	
Medium (M)	95 ± 10	230	
Large (L)	110 ± 10	230	
Extra large (XL)	≥ 110	230	

Table 1 — Dimensions and tolerances

4.3 Watertightness

When gloves are tested for watertightness as described in <u>Annex A</u>, the sample size and allowable number of non-conforming (i.e. leaking) gloves in the sample shall be determined in accordance with the inspection level and AQL given in <u>Table 3</u>.

4.4 Tensile properties

4.4.1 General

Tensile properties shall be measured in accordance with ISO 37, taking three type 2 dumb-bell test pieces from each glove and using the median value as the test result. Test pieces shall be taken from the palm or back of the gloves.

4.4.2 Force at break and elongation at break

When determined in accordance with the method specified in ISO 37, using type 2 dumb-bell test pieces, the force at break and elongation at break shall comply with the requirements given in <u>Table 2</u>, using the inspection level and AQL given in <u>Table 3</u>.

Property	Requirement	
Minimum force at break before accelerated ageing, N	7,0	
Minimum elongation at break before accelerated ageing, %	500	
Minimum force at break after accelerated ageing N.al)	6,0	
Minimum elongation at break after accelerated ageing, %	400	
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Гable 2 —	Tensile	properties
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4.5 Accelerated ageing 85b692d6d97f/iso-25518-2021

Accelerated ageing shall be conducted in accordance with the method specified in ISO 188. Test pieces can be prepared either by ageing the gloves at 70 °C \pm 2 °C for 168 h \pm 2 h or at 100 °C \pm 2 °C for 22 h and cutting the test pieces from the aged gloves or by cutting the test pieces from unaged gloves and ageing the test pieces at 70 °C \pm 2 °C for 168 h \pm 2 h or at 100 °C \pm 2 °C for 22 h. Tensile testing is then conducted as described in 4.4. The results shall comply with the requirements given in Table 2, using the inspection level and AQL as in Table 3. For gloves that are older than 6 months from the date of manufacture or for which the date of manufacture is unknown, no accelerated aging shall be conducted and the tensile properties need only conform to the "after accelerated aging" values in Table 3. The 6-month period should begin with the first day of the month immediately after the one in which the gloves were manufactured.

5 Sampling and inspection

For referee purposes, gloves shall be sampled and inspected in accordance with ISO 2859-1. The inspection levels and acceptance quality limits (AQLs) shall conform to those specified in <u>Table 3</u> for the characteristics listed.

When a lot size cannot be determined, a lot of 35 001 to 150 000 shall be assumed.

Characteristic	Inspection level	AQL
Physical dimensions (width, length)	S-2	6,5
Watertightness	S-4	4,0
Force at break and elongation at break	S-2	6,5

Table 3 — Inspection levels and AQLs

6 Labelling

6.1 Use of symbols

Appropriate international symbols may be used for marking purposes in addition to the wording given. The language used for marking shall be as agreed upon between the interested parties.

6.2 Marking

Packages intended to facilitate safe transport and storage of the gloves shall be clearly marked with the following:

- a) the name or trademark of the manufacturer or supplier;
- b) the material used;
- c) the words "TEXTURED" or "SMOOTH", "POWDERED" or "POWDER-FREE", or words to that effect for the appropriate glove finish;
 - Powdered surface.

NOTE 1 Powdered gloves are gloves which a powder has been applied on as part of the manufacturing process, generally to facilitate donning. Powdered gloves have a maximum powder limit of 15 mg/dm².

Powder free surface. iTeh STANDARD PREVIEW

NOTE 2 Powder-free gloves are gloves which have been manufactured without the deliberate application of powdered materials. Powder-free gloves have a maximum of 2,0 mg powder residue limit per glove.

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- d) the size, as specified in Fableal dards.iteh.ai/catalog/standards/sist/4cde675c-5de1-4ae7-926d-
- 85b692d6d97f/iso-25518-2021
- e) the manufacturer's identifying lot number;
- f) the words "DATE OF MANUFACTURE", or words to that effect, and the year (in four digits) and month of manufacture;
- g) the approximate number of gloves;
- h) instructions for storage;
- i) the words "NOT FOR MEDICAL OR INDUSTRIAL USE", or words to that effect.

Annex A (normative)

Test for watertightness

A.1 Apparatus

A.1.1 Circular hollow mandrel, of minimum external diameter 60 mm and adequate length to hold the glove and, with the glove attached, to accommodate 1 000 cm³ of water. An example is given in Figure A.1.

NOTE A transparent circular hollow mandrel is also suitable.

Dimensions in millimetres



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- 1 hook
- 2 cylinder
- 3 score line on inside surface of wall

Figure A.1 — Mandrel

A.1.2 Holding device, designed to hold the glove in the vertical position when filled with water. An example is given in Figure A.2.



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A.1.3 Graduated cylinder, with a capacity of at least 1/0006 cm 3 dor other dispensing apparatus capable of delivering 1 000 cm³ of water at a time 6d97/iso-25518-2021

A.2 Procedure

Attach the glove to the circular hollow mandrel with a suitable device, e.g. an O-ring, so that the glove does not extend more than 40 mm over the mandrel.

Introduce 1 000 cm³ ± 50 cm³ of water at a maximum temperature of 36 °C into the hollow mandrel. Remove water that has inadvertently splashed onto the outside of the glove. If the water does not rise to within 40 mm of the cuff end, raise the glove to ensure that the whole of the glove, excluding the part 40 mm from the cuff end, is tested. Note any leaks immediately evident. If the glove does not leak immediately, make a second observation for leaks 2 min to 4 min after pouring the water into the glove. Disregard leakage within 40 mm of the cuff end. To assist observation, the water may be coloured with a water-soluble dye.