DUS 883-1

DRAFT UGANDA STANDARD

Second Edition
2021-mm-dd

Single-use medical examination gloves — Part 1: Specification for gloves made from rubber latex or rubber solution

Reference number
WDUS 883 -1: 2021

Compliance with this standard does not, of itself confer immunity from legal obligations

A Uganda Standard does not purport to include all necessary provisions of a contract. Users are responsible for its correct application

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Foreword

Uganda National Bureau of Standards (UNBS) is a parastatal under the Ministry of Tourism, Trade and Industry established under Cap 327, of the Laws of Uganda. UNBS is mandated to co-ordinate the elaboration of standards and is

(a) a member of International Organisation for Standardisation (ISO) and

(b) a contact point for the WHO/FAO Codex Alimentarius Commission on Food Standards, and

(c) the National Enquiry Point on TBT/SPS Agreements of the World Trade Organisation (WTO).

The work of preparing Uganda Standards is carried out through Technical Committees. A Technical Committee is established to deliberate on standards in a given field or area and consists of representatives of consumers, traders, academicians, manufacturers, government and other stakeholders.

Draft Uganda Standards adopted by the Technical Committee are widely circulated to stakeholders and the general public for comments. The committee reviews the comments before recommending the draft standards for approval and declaration as Uganda Standards by the National Standards Council.

The committee responsible for this document is Technical Committee UNBS/TC 307, *Medical devices and equipment*.

This part of WDUS 883 cancels and replaces US 883-1:2011, which has been technically revised.

WDUS 883 consists of the following parts, under the general title Single-use medical examination gloves — Specification

- Part 1: Specification for gloves made from rubber latex or rubber solution
- Part 2: Specification for gloves made from poly (vinyl chloride)

Single-use medical examination gloves — Part 1: Specification for gloves made from rubber latex or rubber solution

WARNING — Persons using this Uganda Standard should be familiar with normal laboratory practices. This standard 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 Draft Uganda Standard, DUS 883-1 specifies requirements and methods of test 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 standard 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 referenced documents are indispensable for the application 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 23529, *Rubber — General procedures for preparing and conditioning test pieces for physical test methods*

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

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

US ISO 15223, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.*

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 http://www.iso.org/obp

4 Classification

4.1 General

Gloves are classified by type and finish, as given in 4.2 and 4.3.

4.2 Type

Two types are classified:

a) type 1: gloves made primarily from natural rubber latex; and

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

4.3 Finish

Four finishes are classified:

a) textured surface over part or all of the gloves;

b) smooth surface;

c) powdered surface;

NOTE 1 Powdered gloves are gloves to which a powder has been applied on the gloves as a part of the manufacturing process, generally to facilitate donning.

Powdered gloves should have a maximum powder limit of 10 mg per glove.

d) Powder-free surface.

NOTE 2 Powder-free gloves are gloves which have been manufactured without the deliberate application of powdered materials. Powder-free is also referred to as “powderless”, “no powder” or “non-powdered”, or other words to that effect. Powder-free gloves have a maximum of 2.0 mg powder residue limit per glove.

NOTE 3 The cuff termination of the glove can be cut or in the form of a rolled rim.

5 Materials

Gloves shall be manufactured from compounded natural rubber or nitrile rubber or polychloroprene rubber latex, or compounded styrene-butadiene rubber or thermoplastic-elastomer solution, or compounded styrene-butadiene rubber emulsion. To facilitate donning the gloves, any surface treatment, lubricant, powder or polymer coating may be used if it is in accordance with US ISO 10993 (all parts).

Any pigment used shall be non-toxic. It is essential that substances used for surface treatment which are capable of being transferred shall be bio-absorbable.

Gloves as supplied to the user shall meet the requirements of the relevant part(s) of US ISO 10993. The manufacturer shall make available to the purchaser, on request, data to support compliance with these requirements.

NOTE 1 Other suitable polymeric materials can be included in future parts of ISO 11193.

NOTE 2 It is recognized that some individuals can, over a period of time, become sensitized to a particular rubber compound (allergic reaction) and require gloves of an alternative formulation.

Limits of extractable proteins, allergenic proteins, residual chemicals, endotoxins and residual powder in gloves may be specified in future editions of this document, subject to the availability of relevant ISO standard test methods.

6 Sampling and selection of test pieces

6.1 Sampling

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

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

Table 1 — Inspection levels and AQLs

Characteristic	Inspection level	AQL
Physical dimensions (width, length, thickness)	S-2	4.0
Water tightness	G-I	2.5
Force at break and elongation at break (before and after accelerated ageing)	S-2	4.0
Physical dimensions (width, length, thickness)	S-2	4.0

6.2 Selection of test pieces

Where test pieces are required, they shall be taken from the palm or back of gloves.

7 Requirements

7.1 Dimensions

When measured at the points shown in Figure 1, gloves shall be in accordance with the dimensions for palm width and length given in Table 2, using the inspection level and AQL given in Table 1.

The measurement of length shall be the shortest distance between the tip of the middle finger and the cuff termination.

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

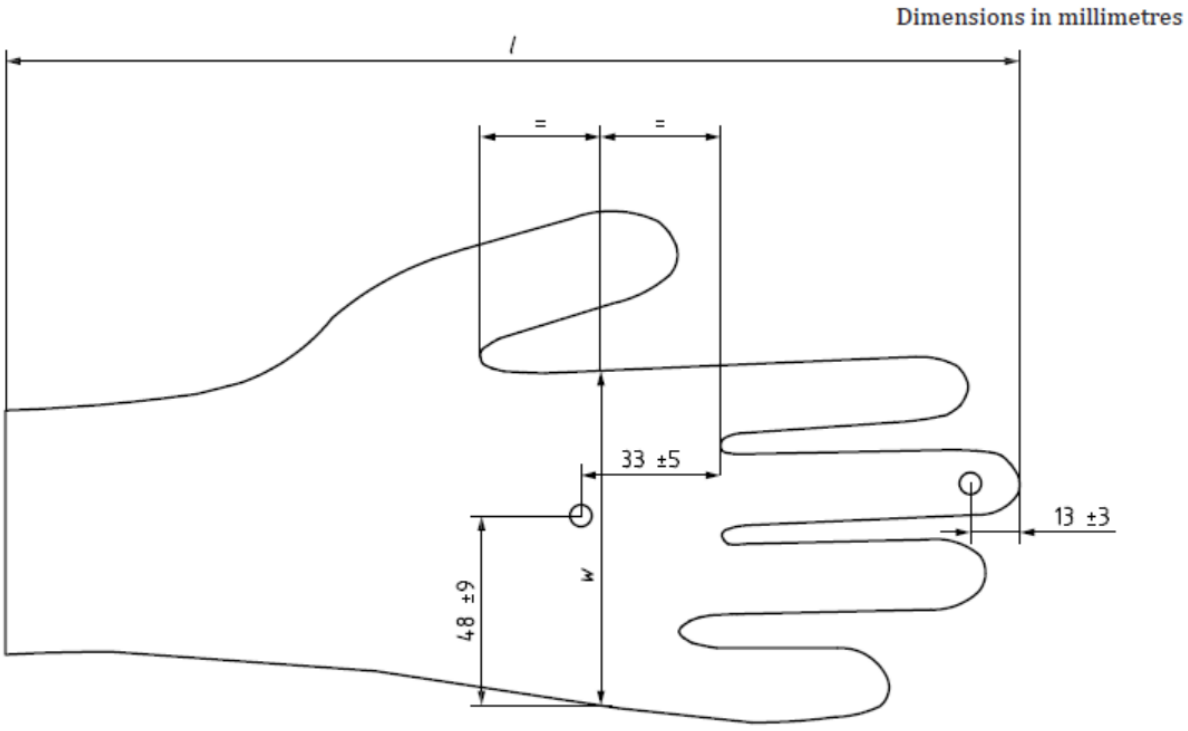
The measurement of width shall be at the midpoint between the base of the index finger and the base of the thumb. The width measurement shall be made with the glove placed on a flat surface.

The thickness of the double wall of an intact glove shall be measured in accordance with ISO 23529, with a pressure on the foot of 22 kPa ± 5 kPa, at each of the locations shown in Figure 1: at a point 13 mm ± 3 mm from the extreme tip of the second finger and at the approximate centre of the palm. The single-wall thickness at each point shall be reported as half the measured double-wall thickness and shall be in accordance with the dimensions given in Table 2, using the inspection level and AQL given in Table 1.

If visual inspection indicates the presence of thin spots, then single-wall thickness measurements shall be made in such areas. The thickness at the smooth area and textured area of a single wall when measured as described in this sub clause shall not be less than 0.08 mm and 0.11 mm, respectively.

Table 2 — Dimensions and tolerances

Size code	Width corresponding to size code (dimension w, Figure 1) mm	Descriptive size	Width corresponding to descriptive size (dimension w, Figure 1), mm	Minimum length (dimension l, Figure 1), mm	thickness (at locations shown in Figure 1), mm	Maximum thickness (at approximate centre of palm), mm
6 and below	≤82	Extra small(X-S)	≤80	220	Smooth area: 0.08 Textured area: 0.11	Smooth area: 2.00 Textured area: 2.03
6 ½	83 ± 5	Small (S)	80 ± 10	220		
7	89 ± 5	Medium (M)	95 ± 10	230		
7 ½	95 ± 5			230		
8	102 ± 6	Large (L)	110 ± 10	230		
8 ½	109 ± 6			230		
9 and above	≥110	Extra large(X-L)	≥110	230		



Key

l length

w width

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

NOTE The distance 48 mm ± 9 mm locates the approximate centre of the palm for different glove sizes.

7.2 Water tightness

When gloves are tested for water tightness as described in Annex A, the sample size and allowable number of non-conforming (leaking) gloves in the sample shall be determined in accordance with the inspection level and AQL given in Table 1.

7.3 Tensile properties

7.3.1 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.

7.3.2 Force at break and elongation at break before accelerated ageing

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 be in accordance with the requirements given in Table 3, using the inspection level and AQL given in Table 1.

7.3.3 Force at break and elongation at break after accelerated ageing

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 ± 2 °C for 168 h ± 2 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 ± 2 °C for 168 h ± 2 h. Tensile testing is then conducted as described in 7.3.2. The results shall be in accordance with the requirements given in Table 3, using the inspection level and AQL given in Table 1.

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.

Table 3 — Tensile properties

Property	Requirement	
	Type 1 glove	Type 2 glove
Minimum force at break before accelerated ageing, N	7.0	7.0
Minimum elongation at break before accelerated ageing, %	650	500
Minimum force at break after accelerated ageing, N	6.0	6.0
Minimum elongation at break after accelerated ageing, %	500	400

7.4 Sterility

If gloves are sterilized, the nature of the sterilization process shall be disclosed.

8 Packaging

If gloves are sterilized, they shall be packaged individually or in pairs packed in unit packs.

9 Labelling

9.1 General

The marking shall include a reference to this document. Appropriate international symbols taken from US ISO 15223-1 and US ISO 15223-2 may be used for labelling in addition to the wording given below.

The language used for marking shall be as agreed upon between the interested parties.

9.2 Unit package

9.2.1 Sterile package

The wrapping for each unit package of an individual glove or pair of gloves shall be clearly marked with the following:

a) name or trademark of the manufacturer or supplier;

b) physical address of the manufacturer

c) material used;

d) words “TEXTURED” or “SMOOTH”, “POWDERED” or “POWDER-FREE” or words to that effect for the appropriate glove finish;

e) size;

f) in the case of gloves that have been treated with any surface-dusting material, a warning note to the effect that surface powder should be aseptically removed prior to use;

g) the manufacturer's identifying lot number;

h) the words “DATE OF MANUFACTURE” or words to that effect, and the year in four digits and month of manufacture;

i) the words “STERILE UNLESS THIS PACKAGE IS OPENED OR DAMAGED”;

j) the words “FOR SINGLE USE” or words to that effect;

k) the words “EXAMINATION GLOVE” (or “EXAMINATION GLOVES”) or “EXAM GLOVE” (or “EXAM GLOVES”);

l) the words “PRODUCT IS MADE FROM NATURAL RUBBER LATEX WHICH MAY CAUSE ALLERGIC REACTIONS” or words to that effect for type 1 gloves and

m) expiry date and condition of storage.

9.2.2 Non-sterile package

The package shall be clearly marked with the following:

a) name or trademark of the manufacturer or supplier;

b) Physical address of manufacturer;

c) material used;

d) words “TEXTURED” or “SMOOTH”, “POWDERED” or “POWDER-FREE” or words to that effect for the appropriate glove finish;

e) size

f) manufacturer's identifying lot number;

g) the words “FOR SINGLE USE” or words to that effect;

h) the words “NON-STERILE”;

i) the words “EXAMINATION GLOVE” (or “EXAMINATION GLOVES”) or “EXAM GLOVE” (or “EXAM GLOVES”);

j) the words “DATE OF MANUFACTURE” or words to that effect, and the year in four digits and month of manufacture;

k) the words “PRODUCT IS MADE FROM NATURAL RUBBER LATEX WHICH MAY CAUSE ALLERGIC REACTIONS” or words to that effect for type 1 gloves and

l) expiry date and condition of storage.

9.3 Multi-unit package

A multi-unit package is one containing a predetermined number of unit packs of the same glove size, intended to facilitate safe transport and storage. Multi-unit packages shall be marked in accordance with 9.2.1 or 9.2.2, with the approximate number of gloves and with the addition of instructions for storage.

Annex A
(normative)

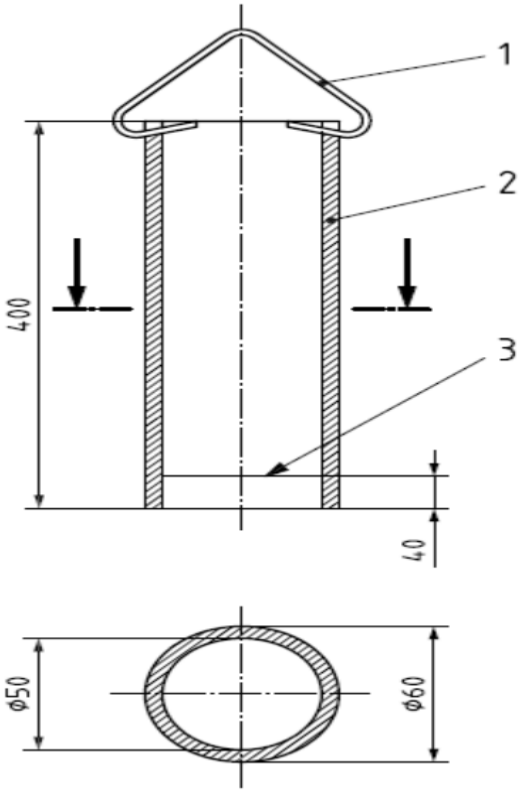
Test for water tightness

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.

N**OTE** A transparent circular hollow mandrel would be suitable.

Dimensions in millimetres



Key

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.

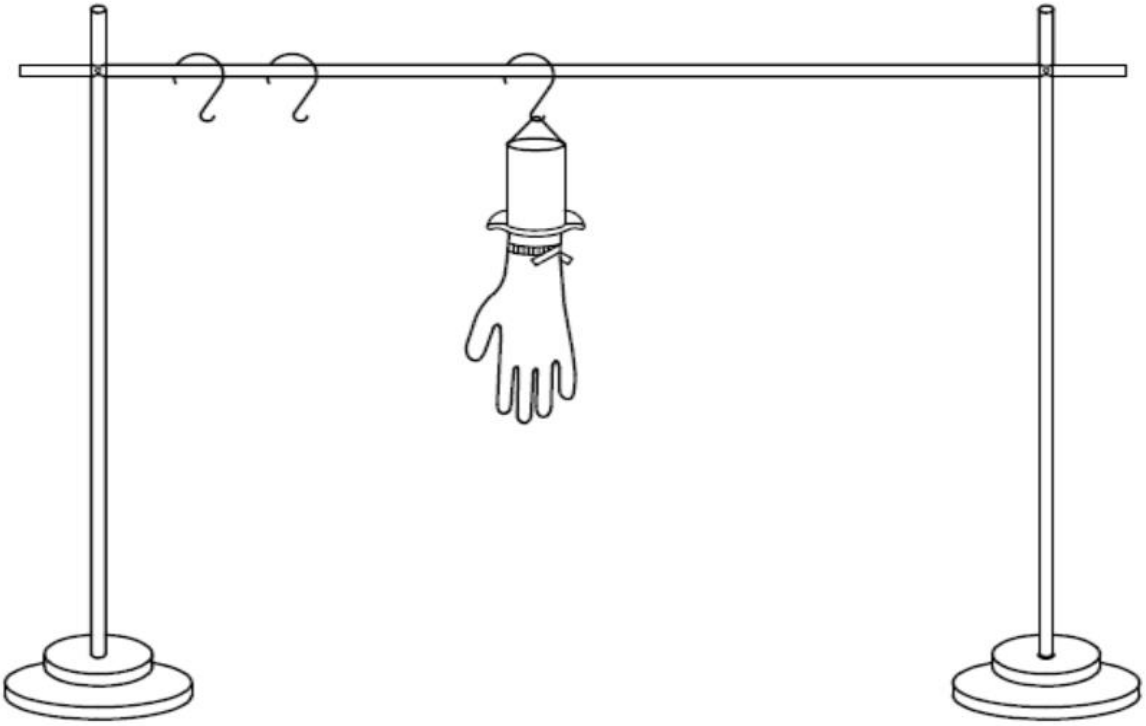


Figure A.2 — Holding device

A.1.3 Graduated cylinder**,** capacity at least 1 000 cm^3, or other dispensing device capable of delivering1 000 cm^3 at a time.

A.2 Procedure

A.2.1 Attach the glove to the circular hollow mandrel by a suitable device, e.g. an O-ring, so that the glove does not extend more than 40 mm over the mandrel.

A.2.2 Introduce 1000 $cm^3 \pm 50$ cm^3 of water, at a maximum temperature of 36 °C, into the device. Remove water that has inadvertently splashed onto the glove. If the water does not rise to within 40 mm of the cuff end, the glove should be raised to ensure that the whole of the glove, excluding the part 40 mm from the cuff end, is tested. Note any leaks that are immediately evident. If the glove does not leak immediately, make a second observation for leaks 2 min to 4 min after pouring 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.

Bibliography

[1] ISO 11193-1:2020, *Single-use medical examination gloves — Part 1: Specification for gloves made from rubber latex or rubber solution*

[2] US 833-1:2011, *Single-use medical examination gloves — Part 1: Specification for gloves made from rubber latex or rubber solution*

Certification marking

Products that conform to Uganda standards may be marked with Uganda National Bureau of Standards (UNBS) Certification Mark shown in the figure below.

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ICS 11.140; 83.140.99

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