DUS 883-2

DRAFT UGANDA STANDARD

Second Edition
2021-mm-dd

Single-use medical examination gloves — Part 2: Specification for gloves made from poly (vinyl chloride)

Reference number
DUS 883: 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 883-2:2011, 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 2: Specification for gloves made from poly (vinyl chloride)

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 part of DUS 883, specifies requirements and test methods for packaged sterile, or bulked non-sterile, poly (vinyl chloride) 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 poly (vinyl chloride) gloves intended for use in handling contaminated medical materials.

This standard is intended as a reference for the performance and safety of poly (vinyl chloride) examination gloves. The safe and proper usage of examination gloves and sterilization procedures with subsequent handling, packaging and storage procedures are outside the scope of this part of Uganda standard.

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

Gloves are classified by finish as follows:

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

b) smooth surface;

c) powdered surface; and

d) powder-free surface.

NOTE 1 Powdered gloves are gloves where a powder has been added as a part of the manufacturing process, generally to facilitate donning. Powder-free gloves are gloves which have been manufactured without the deliberate addition of powdered materials to facilitate donning.

NOTE 2 The cuff termination of the glove may be cut or in the form of a rolled rim.

5 Requirements

5.1 General

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

5.2 Materials

Gloves shall be manufactured from plasticized poly (vinyl chloride). To facilitate donning the gloves, any surface treatment, lubricant, powder or polymer coating may be used.

Any pigment, surface treatment, lubricant, or powder used shall be non-toxic and shall be disclosed on request. It is essential that substances used for surface treatment, which are capable of being transferred, are bio-absorbable.

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

NOTE Limits of extractable plasticizers, residual chemicals and residual powder in gloves may be specified in future editions of this part of Uganda standard, subject to the availability of relevant ISO standard test methods.

5.3 Performance requirements

5.3.1 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.

Table 1 — Inspection levels and AQLs

Characteristics	Inspection level	AQL
Physical dimensions (width, length, thickness)	S-2	4.0
Water tightness	G-1	2.5
Force and elongation at break	S-2	4.0

5.3.2 Tensile properties

5.3.2.1 General

Tensile properties shall be measured in accordance with ISO 37, taking three pieces from each glove and using the median value as the test result. Test pieces shall be taken from the back, palm and terminal palmer surface of the middle finger of the gloves.

5.3.2.2 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 comply with the requirements given in Table 2, using the inspection level and AQL given in Table 1.

5.3.2.3 Force at break and elongation at break after accelerated ageing

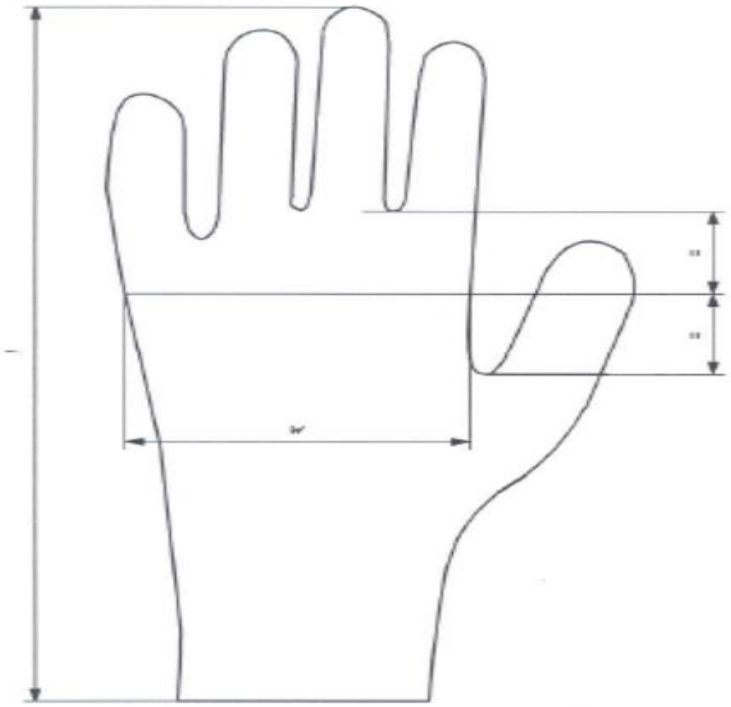
Accelerated ageing shall be conducted in accordance with the method specified in ISO 188. Test pieces can be prepared either by ageing the gloves at 70 °C ± 2 °C for 168 h ± 2 h and cutting the test pieces from the aged gloves, or by cutting the test pieces from un-aged gloves and ageing the test pieces at 70 °C ± 2 °C for 168 h ± 2 h. Tensile testing is then conducted as described in 5.3.2.2. The results shall comply with the requirements given in Table 2, using the inspection level and AQL given in Table 1.

Table 2 — Tensile properties

Property	Requirement
Minimum force at break before accelerated ageing, N	7.0
Minimum elongation at break before accelerated ageing, %	350
Minimum force at break after accelerated ageing, N	7.0
Minimum elongation at break after accelerated ageing, %	350

5.4 Dimensions

When measured at the points shown in Figure 1, gloves shall comply with the dimensions for palm width and length given in Table 3, using the inspection level and AQL given in table 1



Key
l length
w width

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

Table 3 — Dimensions and tolerances

Size code	**Width (dimensions *w*, Figure 1),** mm	**Width (small, medium or large),** mm	**Width by descriptive size (dimensions *w*, Figure 1),** mm	**Minimum length (dimension *l*, Figure 1),** mm	**Minimum thickness (at the locations shown in Figure 2),** mm	**Maximum thickness (at the approximate centre of the palm),** mm
6 and below	≤ 82	Extra small (X-S)	≤80	220	Smooth area: 0.08 Textured area: 0.11	Smooth area: 0.22 Textured area: 0.23
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		

The measurement of length shall be the shortest distance between the tip of the second 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.

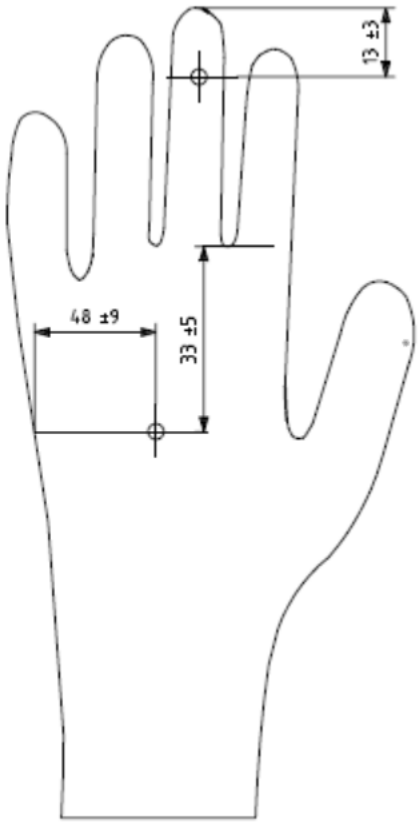
The thickness of the double wall of an intact glove shall be measured in accordance with ISO 23529, with a pressure on the foot of 22 kPa —5 kPa, at each of the locations shown in Figure 2: at a point 13 mm —3 mm from the extreme tip of the second finger and at the approximate centre of the palm. The single-wall thickness at each point shall be reported as half the measured double-wall thickness and shall comply 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 subclause shall not be less than 0.08 mm and 0.11 mm, respectively.

The thickness of the cuff termination, measured in accordance with ISO 23529, should preferably not exceed 2.50 mm.

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

Dimensions in millimetres



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

Figure 2 — Measurement points for the thickness of the glove

5.5 Sterility

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

6 Sampling and selection of test pieces

6.1 Sampling

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

When a lot size cannot be determined, a lot of 35001 to 150000 shall be assumed.

6.2 Selection of test pieces

Where test pieces are required, they shall be taken from the back, palm and tip (Figure 3) of the gloves.

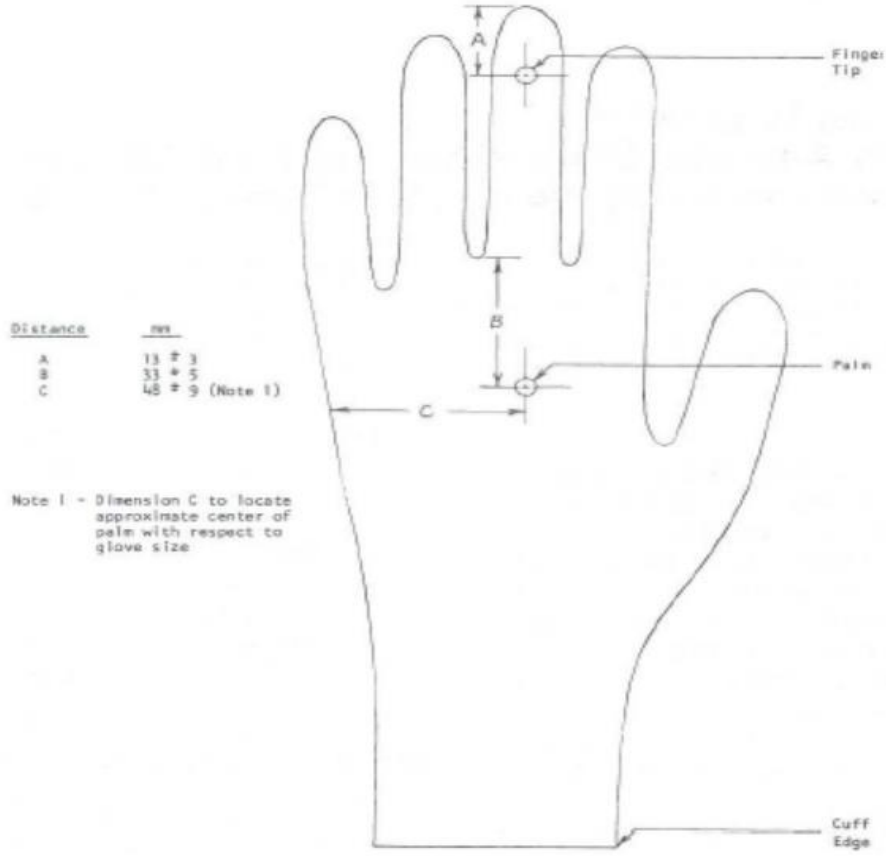


Figure 3 – Approximate location of the palm and finger tip

7 Packaging

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

8 Labelling

8.1 General

Marking shall include a reference to this part of Uganda standard or appropriate international standards and appropriate international symbols taken from US ISO 15223 may be used for labelling.

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

8.2 Unit package

8.2.1 Sterile package

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

a) the name or trademark of the manufacturer or supplier;

b) physical address of manufacturer;

c) the material used;

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

e) the 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 EXPIRY DATE and condition of storage.

j) the words "STERILE UNLESS THIS PACKAGE IS OPENED OR DAMAGED";

k) the words "FOR SINGLE USE" or words to that effect;

l) the words "EXAMINATION GLOVE" (or “EXAMINATION GLOVES”); and

m) the words "Product contains plasticizers (the nature of the plasticizers shall be disclosed) that may be harmful to users".

8.2.2 Non-sterile package

The package shall be clearly marked with the following:

a) the name or trademark of the manufacturer or supplier;

b) Physical address of manufacturer;

c) the material used;

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

e) the size;

f) the 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”)

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

k) the DATE OF EXPIRY and condition of storage; and

l) the words "Product contains plasticizers (the nature of the plasticizers shall be disclosed) that may be harmful to users".

8.3 Multi-unit package

A multi-unit package is one containing a predetermined number of gloves (in unit packs or unpackaged) of the same glove size, intended to facilitate safe transport and storage. Multi-unit packages shall be marked in accordance with 8.2.1 or 8.2.2, with the approximate number of gloves and with the addition of instructions for storage.

Annex A
(normative)

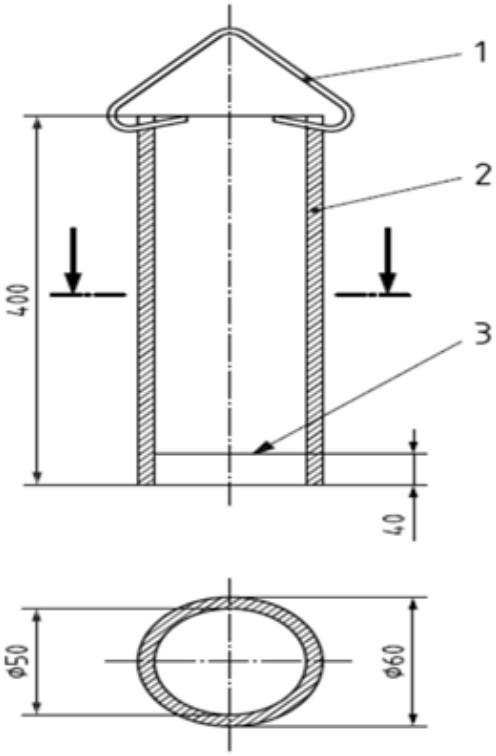
Test for water tightness

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 1000 cm^3 of water. An example is given in Figure A.1.

NOTE — A transparent circular hollow mandrel would be advantageous

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, deigned to hold the glove in the vertical position filled with water. An example is given in Figure A.2.

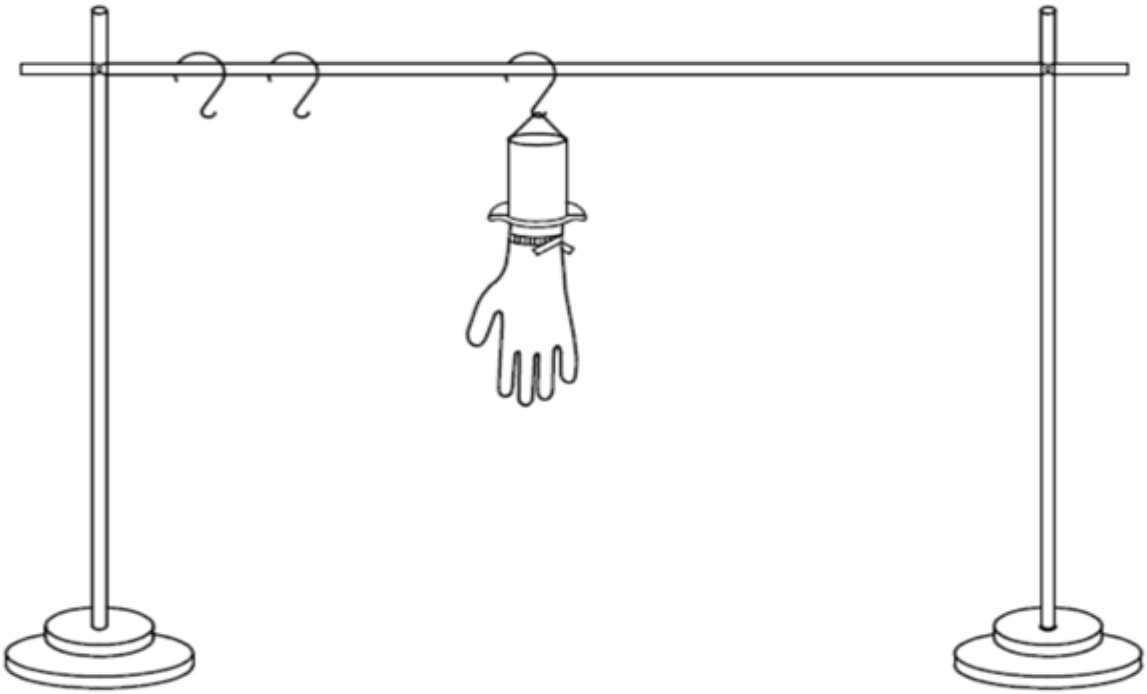


Figure A.2 — Holding device

A.1.3 Graduated cylinder, of capacity at least 1000 cm^3, or other dispensing apparatus capable of delivering 1000 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 ± 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 11193-2:2006, *Single-use medical examination gloves — Part 2: Specification for gloves made from poly (vinyl chloride)*

[2] US 883-2: 2011, *Single-use medical examination gloves — Part 2: Specification for gloves made from poly (vinyl chloride)*

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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