

Single-use medical examination gloves —

Part 1:

Specification for gloves made from rubber latex or rubber solution

KS ISO 11193-1: 2002

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Kenya Medical Research Institute (KEMRI)
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KS ISO 11193-1: 2002

NATIONAL FOREWORD

This Kenya Standard was prepared by the Hospital Equipment Technical Committee, under the guidance of the Health Services Industry Standards Committee, and it is in accordance with the procedures of the Kenya Bureau of Standards.

This standard is identical to and has been reproduced from ISO 11193, Single-use medical examination gloves, Part 1: Specification for gloves made from rubber latex or rubber solution, published by the International Organization for Standardization (ISO). The National Standards Council has endorsed the adoption of the 2002 edition of this standard as a Kenya Standard.

References

For the purposes of this standard, references to International Standards should be replaced by references to the appropriate Kenya Standards, where they have been declared.

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

Gants en caoutchouc pour examen, non réutilisables —

*Partie 1: Spécifications pour gants fabriqués à partir de latex de caoutchouc
ou d'une solution de caoutchouc*



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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.

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 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this part of ISO 11193 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 11193-1 was prepared by Technical Committee ISO/TC 45, *Rubber and rubber products*, Subcommittee SC 4, *Products (other than hoses)*.

This part of ISO 11193 cancels and replaces ISO 11193:1994, which has been technically revised.

ISO 11193 consists of the following parts, under the general title *Single-use medical examination gloves*:

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

Annex A forms a normative part of this part of ISO 11193.

Single-use medical examination gloves —

Part 1:

Specification for gloves made from rubber latex or rubber solution

1 Scope

This part of ISO 11193 specifies requirements 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 part or all of the glove.

This part of ISO 11193 is intended as a reference for the performance and safety of rubber 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 ISO 11193.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 11193. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 11193 are encouraged to investigate the possibility of applying the most recent editions 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 Standards.

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 attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

ISO 4648:1991, *Rubber, vulcanized or thermoplastic — Determination of dimensions 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 labels, labelling and information to be supplied*

3 Classification

3.1 General

Gloves are classified by type and finish, as given in 3.2 and 3.3.

3.2 Type

Two types are classified:

- a) Type 1: gloves made primarily from natural rubber latex;
- 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.

3.3 Finish

Four finishes are classified:

- a) textured surface over part or all of the gloves;
- b) smooth surface;
- c) powdered surface;
- d) powder-free surface.

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

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

4 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 subject to compliance with ISO 10993.

Any pigment used shall be non-toxic. 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 to the purchaser, on request, data to support compliance with these requirements.

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

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

NOTE 3 Limits of extractable proteins, allergenic proteins, residual chemicals, endotoxins and residual powder in gloves may be specified in future editions of this part of ISO 11193, subject to the availability of relevant ISO standard test methods.

5 Sampling and selection of test pieces

5.1 Sampling

For reference 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 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
Watertightness	G-I	2,5
Force at break and elongation at break (before and after accelerated ageing)	S-2	4,0

5.2 Selection of test pieces

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

6 Requirements

6.1 Dimensions

When measured at the points shown in Figure 1, gloves shall comply 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 second finger and the cuff termination.

NOTE 1 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 4648, with a pressure on the foot of $22 \text{ kPa} \pm 5 \text{ kPa}$, at each of the locations shown in Figure 2: a point $13 \text{ mm} \pm 3 \text{ mm}$ from the extreme tip of the second finger and 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.

NOTE 2 The thickness of the cuff termination measured in accordance with ISO 4648 should preferably not exceed 2,50 mm.

6.2 Watertightness

When gloves are tested for watertightness 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.

6.3 Tensile properties

6.3.1 General

Tensile properties shall be measured in accordance with ISO 37, taking three 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 gloves.

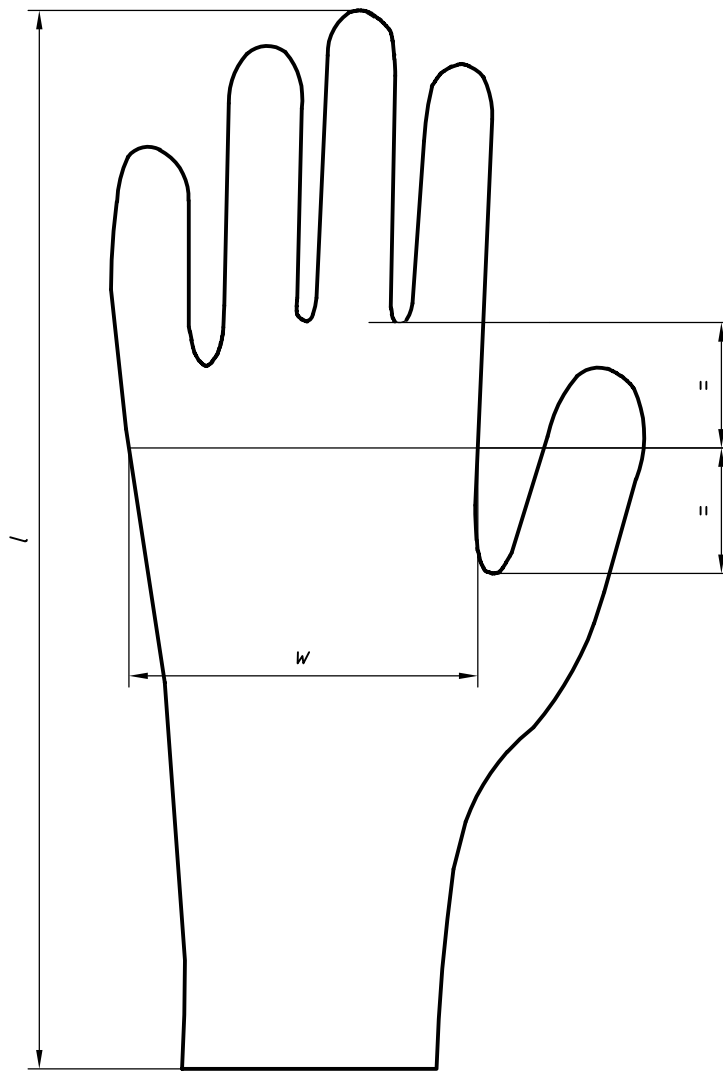
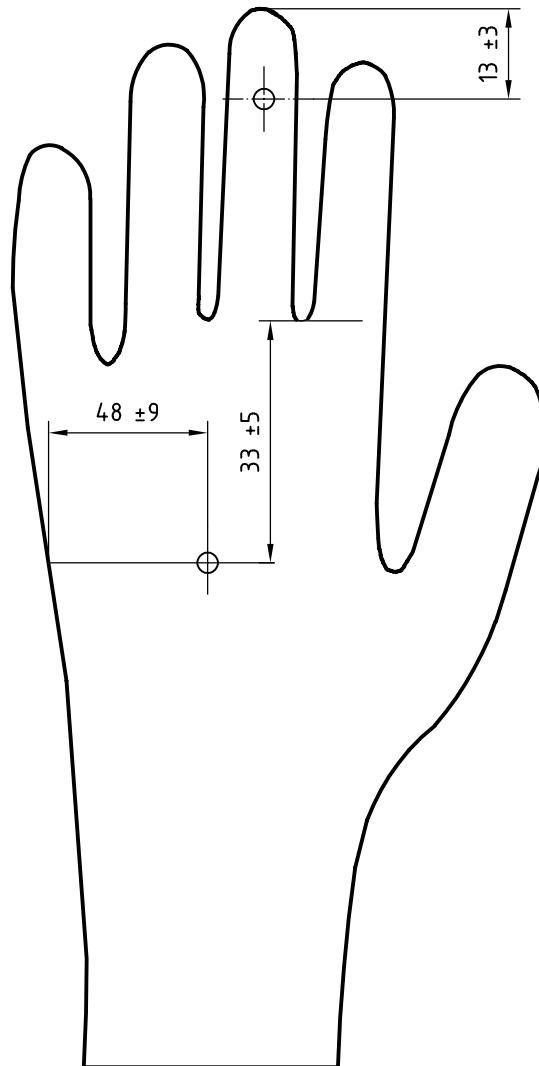


Figure 1 — Measurement points for width and length

Table 2 — Dimensions and tolerances

Size code	Nominal size	Width (dimension 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	Extra small (X-S)	≤ 80	220	For all sizes: Smooth area: 0,08 Textured area: 0,11	For all sizes: Smooth area: 2,00 Textured area: 2,03
6 1/2	Small (S)	80 ± 5	220		
7	Medium (M)	85 ± 5	230		
7 1/2	Medium (M)	95 ± 5	230		
8	Large (L)	100 ± 5	230		
8 1/2	Large (L)	110 ± 5	230		
9 and above	Extra large (X-L)	≥ 110	230		



NOTE The distance $48 \text{ mm} \pm 9 \text{ mm}$ locates the approximate centre of the palm for different glove sizes.

Figure 2 — Measurement points for thickness

6.3.2 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 comply with the requirements given in Table 3, using the inspection level and AQL given in Table 1.

6.3.3 Force at break and elongation at break after accelerated ageing

Accelerated ageing tests shall be conducted in accordance with the method specified in ISO 188. After the test pieces cut from the gloves have been subjected to a temperature of $70 \text{ }^\circ\text{C} \pm 2 \text{ }^\circ\text{C}$ for $168 \text{ h} \pm 2 \text{ h}$, the value of force at break and elongation at break shall comply with the requirements given in Table 3, using the inspection level and AQL given in Table 1.

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	7,0
Minimum elongation at break after accelerated ageing, %	500	400

6.4 Sterility

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

7 Packaging

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

8 Marking

8.1 General

The marking shall include a reference to this part of ISO 11193. Appropriate international symbols taken from 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) the material used;
- c) the words “TEXTURED” or “SMOOTH”, “PRE-POWDERED” or “POWDER-FREE” or words to that effect for the appropriate glove finish;
- d) the size;
- e) 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;
- f) the manufacturer's identifying lot number;
- g) the words “DATE OF MANUFACTURE” or words to that effect, and the year in four digits and month of manufacture;
- h) the words “STERILE UNLESS THIS PACKAGE IS OPENED OR DAMAGED”;
- i) the words “FOR SINGLE USE”;
- j) the words “EXAMINATION GLOVE” (or “EXAMINATION GLOVES”) or “EXAM GLOVE” (or “EXAM GLOVES”);
- k) the words “Product is made from natural rubber latex which may cause allergic reactions” or words to that effect for type 1 gloves.

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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) the material used;
- c) the words “TEXTURED” or “SMOOTH”, “PRE-POWDERED” or “POWDER FREE” or words to that effect for the appropriate glove finish;
- d) the size;
- e) the manufacturer's identifying lot number;
- f) the words “FOR SINGLE USE”;
- g) the words “NON-STERILE”;
- h) the words “EXAMINATION GLOVE” (or “EXAMINATION GLOVES”) or “EXAM GLOVE” (or “EXAM GLOVES”);
- i) the words “DATE OF MANUFACTURE” or words to that effect, and year in four digits and month of manufacture;
- j) the words “Product is made from natural rubber latex which may cause allergic reactions” or words to that effect for type 1 gloves.

8.3 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 8.2.1 or 8.2.2, with the approximate number of gloves and with the addition of instructions for storage.

Annex A
(normative)

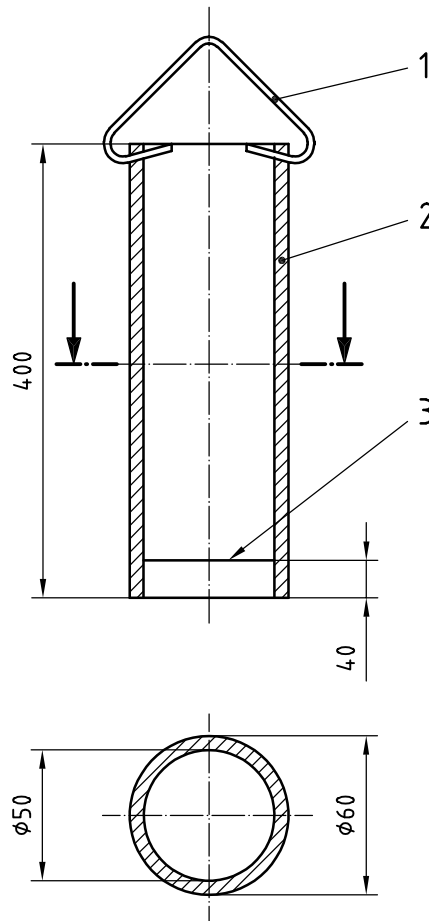
Test for watertightness

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

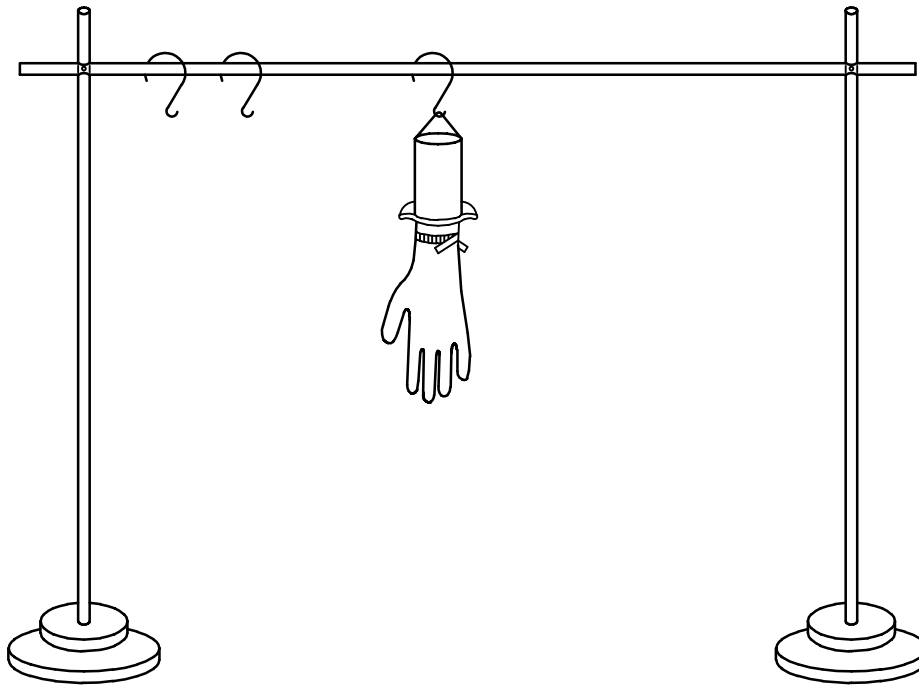


Figure A.2 — Holding device

A.1.3 Graduated cylinder, capacity at least 1 000 cm³, or other dispensing apparatus capable of delivering 1 000 cm³ at a time.

A.2 Procedure

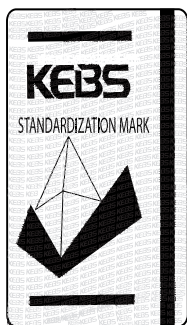
Attach the glove to the circular hollow mandrel by a suitable device, e.g. an O-ring, so that the glove does not extend more than 40 mm over the mandrel.

Introduce 1 000 cm³ ± 50 cm³ of water at a maximum temperature of 36 °C into the device. Remove water that has inadvertently splashed on to 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.

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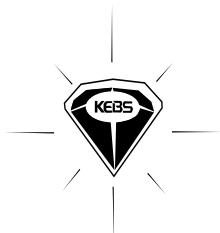
KEBS CERTIFICATION MARKS

1. Product Certification Marks



KEBS Standardization Mark (S-Mark) is issued for use on products that comply with the minimum quality requirements prescribed in Kenya standards. It uses standards as a benchmark for quality compliance and aims at giving manufacturers improved market access and also giving consumers an assurance of quality for the products bearing the mark.

Standardization Mark
SYMBOL FOR PRODUCT QUALITY



Diamond Mark of Quality
SYMBOL FOR PRODUCT QUALITY EXCELLENCE



Import Standardization Mark
SYMBOL FOR PRODUCT QUALITY

2. Systems Certification Marks



ISO 9001 REGISTERED FIRM
QUALITY MANAGEMENT SYSTEM



OCCUPATIONAL HEALTH AND SAFETY
OHSAS 18001



ISO 14001 REGISTERED FIRM
ENVIRONMENTAL MANAGEMENT SYSTEM



ISO 22000 REGISTERED FIRM
FOOD & SAFETY MANAGEMENT SYSTEM

KEBS is mandated to provide Standardization, Metrology and Conformity Assessment Services through:

- Promotion of standardization in commerce and industry
- Provision of testing and calibration facilities
- Control of the use of standardization marks
- Undertaking educational work in standardization
- Facilitation of the implementation and practical application of standards
- Maintenance and dissemination of the International System of Units (SI) of measurements

KEBS offers the following services:

- Standards development and harmonization
- Testing services
- Measurement services (Calibration)
- Enforcement of standards
- Product inspection services
- Education and Training in Standardization, Metrology and Conformity Assessment
- Product and Management Systems Certification Services

INFORMATION ON STANDARDS

Standards are documents that provide a common reference point for the assessment of the quality of goods and services. Standards facilitate transparency in the exchange of products and enhance market access of Kenyan products into local, regional and international markets.

Information on standards and related documents is available at the KEBS standards information centre.

KEBS houses the WTO-TBT National Enquiry Point (NEP) which disseminates notification likely to affect international trade to the industry.

KEBS also provides technical advice on installation and improvement of quality goods and services to the industry so as to facilitate efficient implementation of standards. Some of the advantages of standards include: enhancement of quality assurance, safety and environmental protection measures, minimization of wastage, reduction of costs and unnecessary varieties and promotion of interchangeability and increased productivity in industry.

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