BRITISH STANDARD

BS EN 455-2:2009
+A2:2013

Medical gloves for single use

Part 2: Requirements and testing for physical properties

ICS 11.140

British Standards

National foreword

This British Standard is the UK implementation of EN 455-2:2009+A2:2013. It supersedes BS EN 455-2:2009+A1:2011, which is withdrawn.

The UK committee, CH/205/3, recognizes that this British Standard specifies new minimum requirements for the force at break for gloves made from natural rubber latex compared to previous editions of the standard. This does not prevent Purchasers who wish to do so continuing to specify higher values in contract negotiations.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to CEN text carry the number of the CEN amendment. For example, text altered by CEN amendment A1 is indicated by 〉A1〈.

The UK participation in its preparation was entrusted by Technical Committee CH/205, Non-active medical devices, to Subcommittee CH/205/3, Medical gloves.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 November 2009

ISBN 978 0 580 82252 0

Amendments/corrigenda issued since publication

Date	Comments
31 October 2011	Implementation of CEN amendment A1:2011
30 April 2013	Implementation of CEN amendment A2:2013

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 455-2:2009+A2

February 2013

ICS 11.140

Supersedes EN 455-2:2009+A1:2011

English Version

Medical gloves for single use - Part 2: Requirements and testing for physical properties

Gants médicaux non réutilisables - Partie 2: Propriétés physiques: Exigences et essais

Medizinische Handschuhe zum einmaligen Gebrauch - Teil 2: Anforderungen und Prüfung der physikalischen Eigenschaften

This European Standard was approved by CEN on 3 October 2009 and includes Amendment 1 approved by CEN on 3 January 2011 and Amendment 2 approved by CEN on 8 January 2013.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN 455-2:2009+A2:2013: E

Contents

Page

Foreword

This document (EN 455-2:2009+A2:2013) has been prepared by Technical Committee CEN/TC 205 "Non-active medical devices", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2013, and conflicting national standards shall be withdrawn at the latest by August 2013.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes A2 EN 455-2:2009+A1:2011 A2.

This document includes Amendment 1, approved by CEN on 2011-01-03 and Amendment 2, approved by CEN on 2013-01-08.

The start and finish of text introduced or altered by amendment is indicated in the text by tags A1 A1 and A2 A2.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

EN 455 consists of the following parts, under the general title *Medical gloves for single use*:

— *Part 1: Requirements and testing for freedom from holes*

— *Part 2: Requirements and testing for physical properties*

— *Part 3: Requirements and testing for biological evaluation*

— *Part 4: Requirements and testing for shelf life determination*

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

1 Scope

This European Standard specifies requirements and gives test methods for physical properties of single-use medical gloves (i.e. surgical gloves and examination/procedure gloves) in order to ensure that they provide and maintain in use an adequate level of protection from cross contamination for both patient and user.

This standard does not specify the size of a lot. Attention is drawn to the difficulties that can be associated with the distribution and control of very large lots. The recommended maximum individual lot size for production is 500 000.

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 188, *Rubber, vulcanized or thermoplastic — Accelerated ageing and heat resistance tests*

ISO 23529:2004, *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.

3.1
medical gloves for single use
gloves intended for use in the medical field to protect patient and user from cross-contamination

3.2
surgical gloves
sterile, anatomically shaped medical gloves with the thumb positioned towards the palmar surface of the index finger rather than laying flat, and intended for use in invasive surgery

3.3
examination gloves
procedure gloves
sterile or non-sterile medical gloves, which may or may not be anatomically shaped, intended for conducting medical examinations, diagnostic and therapeutic procedures and for handling contaminated medical material

3.4
lot
collection of gloves of the same design, colour, shape, size and formulation, manufactured at essentially the same time, using the same process, raw materials of the same specifications, common equipment and packed in the same type of individual container

[EN 455-4:2009]

4 Dimensions

4.1 General

When measured as described in 4.2 and 4.3 taking 13 samples from each lot, the median value obtained for the dimensions shall be as given in Tables 1 and 2.

4.2 Length

Measure the length (dimension *l*, as designated in Figure 1) by freely suspending the glove with the middle finger on a vertical graduated rule having a rounded tip so as to fit the shape of the finger tip of the glove. Remove wrinkles and folds without stretching the glove. Record the median measured length.

NOTE For greater ease of measurement, the ruler may be angled backwards slightly so that the glove is in contact with the ruler.

4.3 Width

Measure the width (dimension *w*, as designated in Figure 1), to the nearest mm, using a ruler, with the glove placed on a flat surface. Do not stretch the glove.

Table 1 — Dimensions of surgical gloves

Size	Median length[a] in mm	Median width[b c] in mm
5	≥ 250	67 ± 4
5,5	≥ 250	72 ± 4
6	≥ 260	77 ± 5
6,5	≥ 260	83 ± 5
7	≥ 270	89 ± 5
7,5	≥ 270	95 ± 5
8	≥ 270	102 ± 6
8,5	≥ 280	108 ± 6
9	≥ 280	114 ± 6
9,5	≥ 280	121 ± 6

a Dimension *l* as designated in Figure 1.

b Dimension *w* as designated in Figure 1.

c The width requirements are for gloves made from natural rubber latex and all other elastomeric materials. These dimensions may not be appropriate for gloves made from other materials.

Table 2 — Dimensions of examination/procedure gloves

Size	Median length [a] in mm	Median width [b c] in mm
Extra Small	≥ 240	≤ 80
Small		80 ± 10
Medium		95 ± 10
Large		110 ± 10
Extra Large		≥ 110

NOTE Manufacturers may optionally use the sizes and dimensions given in Table 1 in order to provide a wider range of glove sizes.

[a] Dimension *l* as designated in Figure 1.

[b] Dimension *w* as designated in Figure 1.

[c] The width requirements are for gloves made from natural rubber latex and all other elastomeric materials. These dimensions may not be appropriate for gloves made from other materials.

5 Strength

5.1 General

Different glove materials require different force at break requirements to ensure an acceptable performance. Absolute force at break values do not directly correlate with the in use performance. Selection of appropriate glove materials for the intended application shall be part of the risk management process.

When the strength of the glove is tested as described in 5.2 at a temperature of (23 ± 2) °C and a relative humidity of (50 ± 5) % r.h. the force at break of gloves shall be as given in Table 3.

5.2 Force at break

5.2.1 Ageing and shelf life requirements are described in EN 455-4.

5.2.2 Obtain one dumb-bell test piece from each of 13 gloves taken from a single lot (from seven pairs of gloves where applicable) using a cutter as specified in Figure 2 from the palm, back of the hand or cuff areas of each glove in the test sample, avoiding textured areas if possible and taking the test pieces in the direction of the longitudinal axis of the glove.

5.2.3 Determine the force at break of the 13 test pieces after conditioning for a minimum of 16 h. The tensometer should be equipped with a load cell appropriate for the strength of the sample under test, with jaws that firmly grip but do not damage the test specimen and with a crosshead speed of 500 mm/min.

NOTE If a test piece breaks at the shoulder, it is not necessary to repeat the test on another test piece.

5.2.4

a) Determine the single wall thickness (t_f) of the same glove as in 5.2.2 at a point on the middle finger within (13 ± 3) mm of the finger tip by measuring the double wall thickness as described in method A of ISO 23529:2004, using a gauge with a foot pressure of (22 ± 5) kPa. Take the single wall thickness as one half of the measured double wall thickness.

b) Measure the thickness of the dumb-bell test pieces (t_x) as described in method A of ISO 23529:2004, using the gauge described in 5.2.4 a).

c) Compare the values of t_f and t_x. If $t_f/t_x \geq 0{,}9$, no correction to the measured force at break is necessary. If $t_f/t_x < 0{,}9$, correct the measured value by multiplying the measured force at break (see 5.2.3) by a factor of t_f/t_x.

NOTE Although there is no requirement for thickness in this standard, it is recognised that the fingers of a glove may, because of design or manufacturing processes, be significantly thinner and therefore weaker in terms of force to break than at the points from which the test pieces were taken. It is important to ensure that the minimum force at break requirements given in Table 3 are maintained at the fingertips. If the difference in thickness between the fingertip and the point from which the test pieces were taken is small (less than 10 %), no correction is necessary. If this difference is greater than 10 %, a correction factor based on the relative thickness is applied to the measured force at break to obtain a true estimate of the strength of the glove at the fingertip.

5.2.5 Record the force at break, in N, for each of the 13 samples, corrected as described in 5.2.4 if necessary. The median of the recorded results shall comply with the values of Table 3.

[A1] Table 3 — Median values of force at break

	Force at break in Newton				
	Surgical gloves		Examination/procedure gloves		
	a)	b)	c)	d)	e)
Throughout shelf life tested according to 5.2 and within 12 months of manufacture tested according to 5.3	≥ 9,0	≥ 9,0	≥ 6,0	≥ 6,0	≥ 3,6

a) Requirements for gloves made from natural rubber latex.

b) Requirements for gloves made from all other elastomeric materials, e.g. polychloroprene, synthetic polyisoprene, nitrile, styrene block copolymers, polyurethane.

c) Requirements for gloves made from elastomeric materials except nitrile, e.g. natural rubber latex, polychloroprene, synthetic polyisoprene, styrene block copolymers, polyurethane.

d) Requirements for gloves made from nitrile.

e) Requirements for gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).

[A1]

5.3 Force at break after challenge testing

5.3.1 Place gloves packaged in unit packages or gloves taken from bulk packages for a period of seven days at a temperature of (70 ± 2) °C in an oven as specified in ISO 188.

5.3.2 Measure the force at break as described in 5.2.

6 Test report

Any test report shall include at least the following information:

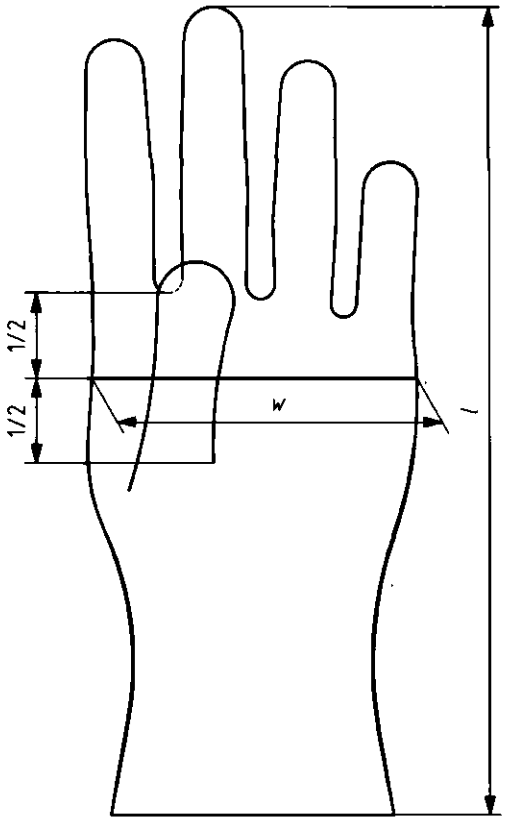
a) reference to this part of EN 455;

b) the type of glove and the manufacturing batch code;

c) the name and address of the manufacturer or distributor and test laboratory, if different;

d) the date of testing performed;

e) the test results.

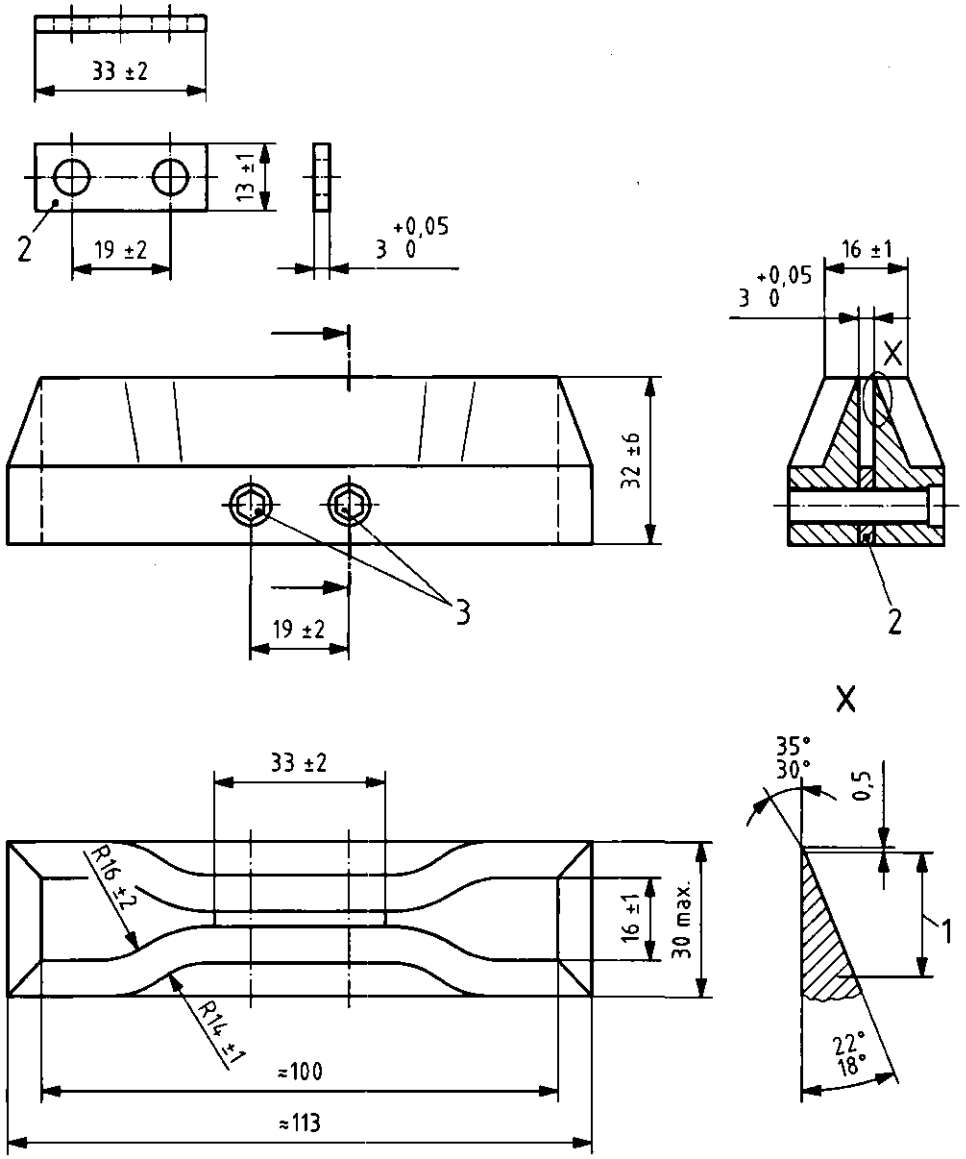


Key

w width
l length

Figure 1 — Designation of length and width of gloves

Dimensions in millimetres



Key

1 grind 6 mm/min.
2 spacer
3 bolts

Figure 2 — Cutter for dumb bell specimens

Annex ZA
(informative)

A2 Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC concerning Medical Devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC concerning medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC concerning medical devices

Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4, 5, 5.2	9.2	

For devices intended by the manufacturer to be for dual use in accordance with Article 1(6) of Directive 93/42 EEC the following Table ZA.2 details the relevant Essential Requirements of Directive 89/686/EC on Personal Protective Equipment and their corresponding clauses of this European Standard. Table ZA.2, however, does not imply any citation in the OJEU under the PPE Directive and thus does not provide presumption of conformity for the PPE Directive.

Table ZA.2 — Relevant Essential Requirements from Directive 89/686/EEC on Personal Protective Equipment that are addressed by this European Standard
(according to Article 1(6) of amended Directive 93/42/EEC)

Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 89/686/EEC	Qualifying remarks/Notes
4	1.1.1	
5	1.3.2	
5.2	2.4	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard. A2

BSI - British Standards Institution

BSI is the independent national body responsible for preparing British Standards. It presents the UK view on standards in Europe and at the international level. It is incorporated by Royal Charter.

Revisions

British Standards are updated by amendment or revision. Users of British Standards should make sure that they possess the latest amendments or editions.

It is the constant aim of BSI to improve the quality of our products and services. We would be grateful if anyone finding an inaccuracy or ambiguity while using this British Standard would inform the Secretary of the technical committee responsible, the identity of which can be found on the inside front cover. Tel: +44 (0)20 8996 9000. Fax: +44 (0)20 8996 7400.

BSI offers members an individual updating service called PLUS which ensures that subscribers automatically receive the latest editions of standards.

Buying standards

Orders for all BSI, international and foreign standards publications should be addressed to Customer Services. Tel: +44 (0)20 8996 9001. Fax: +44 (0)20 8996 7001 Email: orders@bsigroup.com You may also buy directly using a debit/credit card from the BSI Shop on the Website http://www.bsigroup.com/shop

In response to orders for international standards, it is BSI policy to supply the BSI implementation of those that have been published as British Standards, unless otherwise requested.

Information on standards

BSI provides a wide range of information on national, European and international standards through its Library and its Technical Help to Exporters Service. Various BSI electronic information services are also available which give details on all its products and services. Contact Information Centre. Tel: +44 (0)20 8996 7111 Fax: +44 (0)20 8996 7048 Email: info@bsigroup.com

Subscribing members of BSI are kept up to date with standards developments and receive substantial discounts on the purchase price of standards. For details of these and other benefits contact Membership Administration. Tel: +44 (0)20 8996 7002 Fax: +44 (0)20 8996 7001 Email: membership@bsigroup.com

Information regarding online access to British Standards via British Standards Online can be found at http://www.bsigroup.com/BSOL

Further information about BSI is available on the BSI website at http://www.bsigroup.com

Copyright

BSI Group
Headquarters 389
Chiswick High Road,
London, W4 4AL, UK
Tel +44 (0)20 8996 9001
Fax +44 (0)20 8996 7001
www.bsigroup.com/
standards