BRITISH STANDARD

BS EN 455-2 : 1995

Implementing Amendments No. 1 and 2, not published separately

Medical gloves for single use

Part 2. Specification for physical properties

The European Standard EN 455-2 : 1995 has the status of a British Standard

ICS 11.140

Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee HCC/6, Rubber products for hospital use, upon which the following bodies were represented:

Association of Clinical Pathologists
British Rubber Manufacturers Association Ltd.
British Surgical Trades Association
Department of Health
Guild of Hospital Pharmacists
Infection Control Nurses Association
Joint Committee of Professional Nursing, Midwifery and Health Visiting Associations (England)
Malaysian Rubber Producers Research Association
Medical Sterile Products Association
National Association of Glove Manufacturers
National Association of Theatre Nurses

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on 15 December 1995

The following BSI references relate to the work on this standard:
Committee reference HCC/6
Draft for comment 91/55202 DC

ISBN 0 580 24711 2

Amendments issued since publication

Amd. No.	Date	Text affected
9284	December 1996	Figure 2
9984	May 1998	See national foreword

Summary of pages

The following table identifies the current issue of each page. Issue 1 indicates that a page has been introduced for the first time by amendment. Subsequent issue numbers indicate an updated page.

Page	Issue	Page	Issue
Front cover	3	3	original
Inside front cover	3	4	original
a	2	5	original
b	blank	6	3
i	2	7	1
ii	3	8	blank
EN title page	3	Inside back cover	original
2	2	Back cover	original

Contents

National foreword

This British Standard has been prepared by Technical Committee HCC/6 and is the English language version of EN 455-2 : 1995 *Medical gloves for single use — Part 2: Requirements and testing for physical properties*, including amendment A1 : 1998 published by the European Committee for Standardization (CEN). It includes the corrigendum dated June 1996. EN 455-2 was produced as a result of international discussions in which the United Kingdom took an active part.

Attention is drawn to BS EN 455-1, which gives requirements and tests for freedom from holes, for medical gloves for single use, and to BS 4005, which gives requirements for single-use sterilized surgical rubber gloves.

Cross-references

Publication referred to	Corresponding British Standard
	BS 903 *Physical testing of rubber*
ISO 37 : 1994	Part A2 : 1995 *Method for determination of tensile stress-strain properties*
ISO 188 : 1982	Part A19 : 1986 *Heat resistance and accelerated ageing tests*
ISO 2859-1 : 1989	BS 6001 *Sampling procedures for inspection by attributes* Part 1 : 1991 *Specification for sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection*
ISO 4648 : 1991	BS 903 *Physical testing of rubber* Part A38 : 1991 *Methods for the determination of dimensions of test pieces and products for test purposes*

Amendment No. 2
Figure 2 has been replaced and annex ZA has been added.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 455-2

February 1995

+A1

January 1998

ICS 11.140; 13.340.10

Incorporates corrigendum June 1996

Descriptors: glove, medical glove, medical glove for single use, physical properties

English version

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

(includes amendment A1 : 1998)

Gants médicaux non réutilisables — Partie 2: Propriétes physiques: Prescriptions et essais (inclut l'amendement A1 : 1998)

Medizinische Handschuhe zum einmaligen Gebrauch — Teil 2: Anforderungen und Prüfung der physikalischen Eigenschaften (enthält Änderung A1 : 1998)

This European Standard was approved by CEN on 1995-02-01. 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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Foreword

This European Standard has been prepared by the Technical Committee CEN/TC 205, Non-active medical devices, the secretariat of which is held by BSI.

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

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 1995, and conflicting national standards shall be withdrawn at the latest by October 1995.

According to the CEN/CENELEC Internal Regulations, the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom.

Foreword to amendment A1

This Amendment EN 455-2 : 1995/A1 : 1998 to EN 455-2 : 1995 has been prepared by Technical Committee CEN/TC 205, Non-active medical devices, the Secretariat of which is held by BSI.

This Amendment to the European Standard EN 455-2 : 1995 shall be give the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 1998, and conflicting national standards shall be withdrawn at the latest by July 1998.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

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

1 Scope

This Part of this 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.

2 Normative references

This European Standard incorporates, by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references, the latest edition of the publication referred to applies.

ISO 37 : 1977	*Rubber, vulcanized — Determination of tensile stress-strain properties*
ISO 188 : 1982	*Rubber, vulcanized — Accelerated ageing or heat-resistance tests*
ISO 554 : 1976	*Standard atmospheres for conditioning and/or testing — Specifications*
ISO 2859-1 : 1989	*Sampling procedures for inspection by attributes — Part 1: Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection*
ISO 4648 : 1991	*Rubber, vulcanized or thermoplastic — Determination of dimensions of test pieces and products for test purposes*

3 Definitions

For the purposes of this standard the following 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 lying flat, and intended for use in invasive surgery.

3.3 examination/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 long-cuff medical gloves

a) Surgical gloves having a minimum overall length of 300 mm.

b) Examination/procedure gloves having a minimum overall length of 270 mm.

3.5 seamed medical gloves; welded gloves

Medical gloves manufactured by welding or otherwise bonding together flat films of material.

4 Dimensions

4.1 General

When measured as described in **4.2** and **4.3**, the dimensions shall be as given in tables 1 and 2.

Table 1. Dimensions of surgical gloves

Size	Minimum length[1] mm	Width[2)3)] 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

[1] Dimension l as designated in figure 1.
[2] Dimension w as designated in figure 1.
[3] The width requirements are for gloves made from natural rubber latex, synthetic rubber latex or solutions of natural and/or synthetic rubber. These dimensions may not be appropriate for gloves made from other materials.

Table 2. Dimensions of examination/procedure gloves

Size	Minimum length[1] mm		Width[2)3)] mm
	Seamed gloves	Unseamed gloves	
Extra small	270	240	≤ 80
Small	270	240	80 ± 10
Medium	270	240	95 ± 10
Large	270	240	110 ± 10
Extra large	270	240	≥ 110

[1] Dimension l as designated in figure 1.
[2] Dimension w as designated in figure 1.
[3] The width requirements are for gloves made from natural rubber latex, synthetic rubber latex or solutions of natural and/or synthetic rubber. These dimensions may not be appropriate for gloves made from other materials.

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 length, to the nearest millimetre, to the edge of the cuff.

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

4.3 Width

Measure the width (dimension w, as designated in figure 1), to the nearest millimetre, using a rule, with the glove placed on a flat surface. Do not stretch the glove.

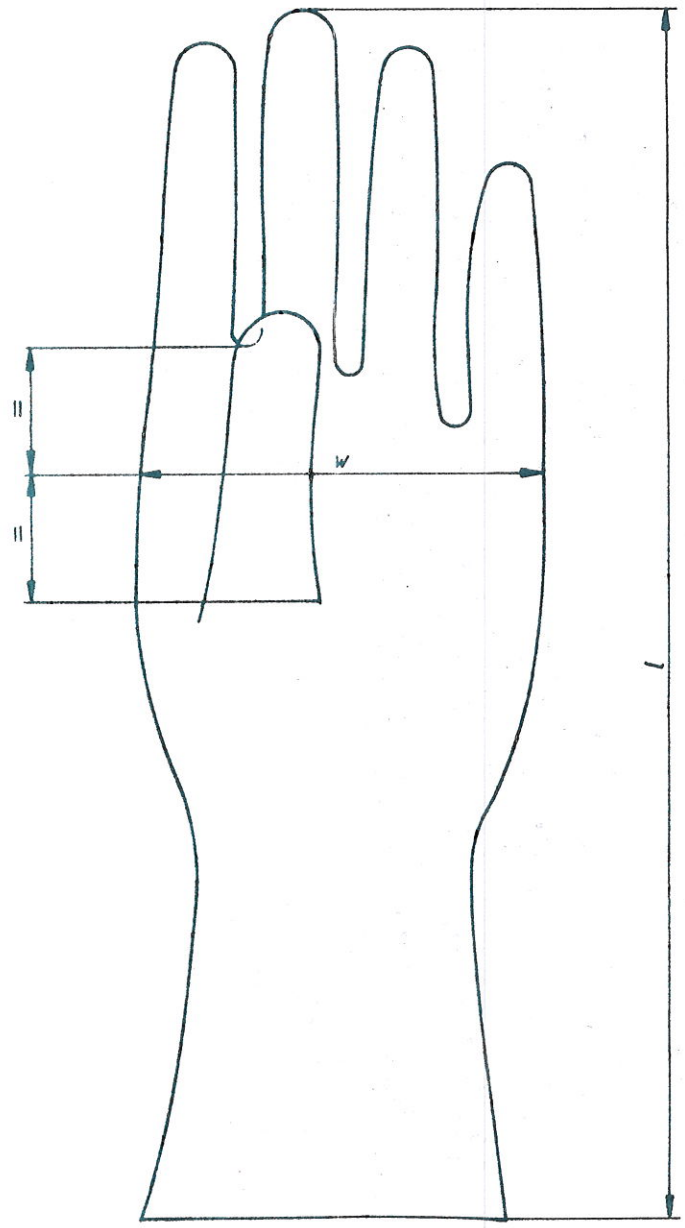

Figure 1. Designation of length and width of gloves

5 Strength

5.1 General

When tested as described in **5.2**, **5.3** and, if appropriate, **5.4** at a temperature of (23 ± 2) °C and a relative humidity of (50 ± 5) % r.h., the force at break of seamed and unseamed gloves and the seam strength of seamed gloves shall be as given in table 3.

5.2 Force at break before accelerated ageing

5.2.1 Obtain three dumb-bell test pieces, 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.

5.2.2 Determine the force at break of each test piece as described in ISO 37, using an extension rate 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.

5.2.3

a) Determine the single wall thickness (t_f) of the same glove as in **5.2.1** 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 A1 of ISO 4648, 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 A1 of ISO 4648, using the gauge described in **5.2.3**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 **5.2.2**) by a factor of t_f / t_x.

NOTE. Although there is no requirement for thickness in this standard, it is recognized that the fingers of a glove may, because of design or manufacturing processes, be significantly thinner and therefore significantly weaker in terms of force at break than at the points from which the test pieces were taken. It is important to ensure that the minimum strength 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.

5.2.4 Record the median force at break, in newtons, for each glove, corrected as described in **5.2.3** if necessary.

5.3 Force at break after accelerated ageing

5.3.1 Place gloves packaged in unit packages or gloves taken from bulk packages in a normal oven as specified in ISO 188 for a period of 7 days at a temperature of (70 ± 2) °C.

5.3.2 Measure the force at break as described in **5.2.**

5.4 Seam strength of seamed gloves

5.4.1 Obtain three dumb-bell test pieces, using a cutter as specified in figure 2, from each glove in the test sample such that the seam is present within the length of the narrow parallel portion of the test piece and is at right angles to the long axis of the test piece.

5.4.2 Determine the force at break of each test piece as described in **5.2.2.**

5.4.3 Record the median force at break, in newtons, for each glove.

5.4.4 Repeat **5.4.1** to **5.4.3** on gloves that have been aged as described in **5.3.1.**

Table 3. Force at break and seam strength

Values in newtons

	Surgical gloves		Examination/procedure gloves	
	Latex[1]	Synthetic[2]	Latex[3]	Other materials
Minimum force at break before accelerated ageing	10,5	7,5	7,5	3
Minimum force at break after accelerated ageing	7,5	5,5	5,5	3
Minimum seam strength of seamed gloves before accelerated ageing	10,5	7,5	7,5	3
Minimum seam strength of seamed gloves after accelerated ageing	7,5	5,5	5,5	3

[1] Requirements for gloves made from natural rubber latex.

[2] Requirements for gloves made from synthetic rubber latex or solutions of natural or synthetic rubber.

[3] Requirements for gloves made from natural rubber latex, synthetic rubber latex or solutions of natural and/or synthetic rubber.

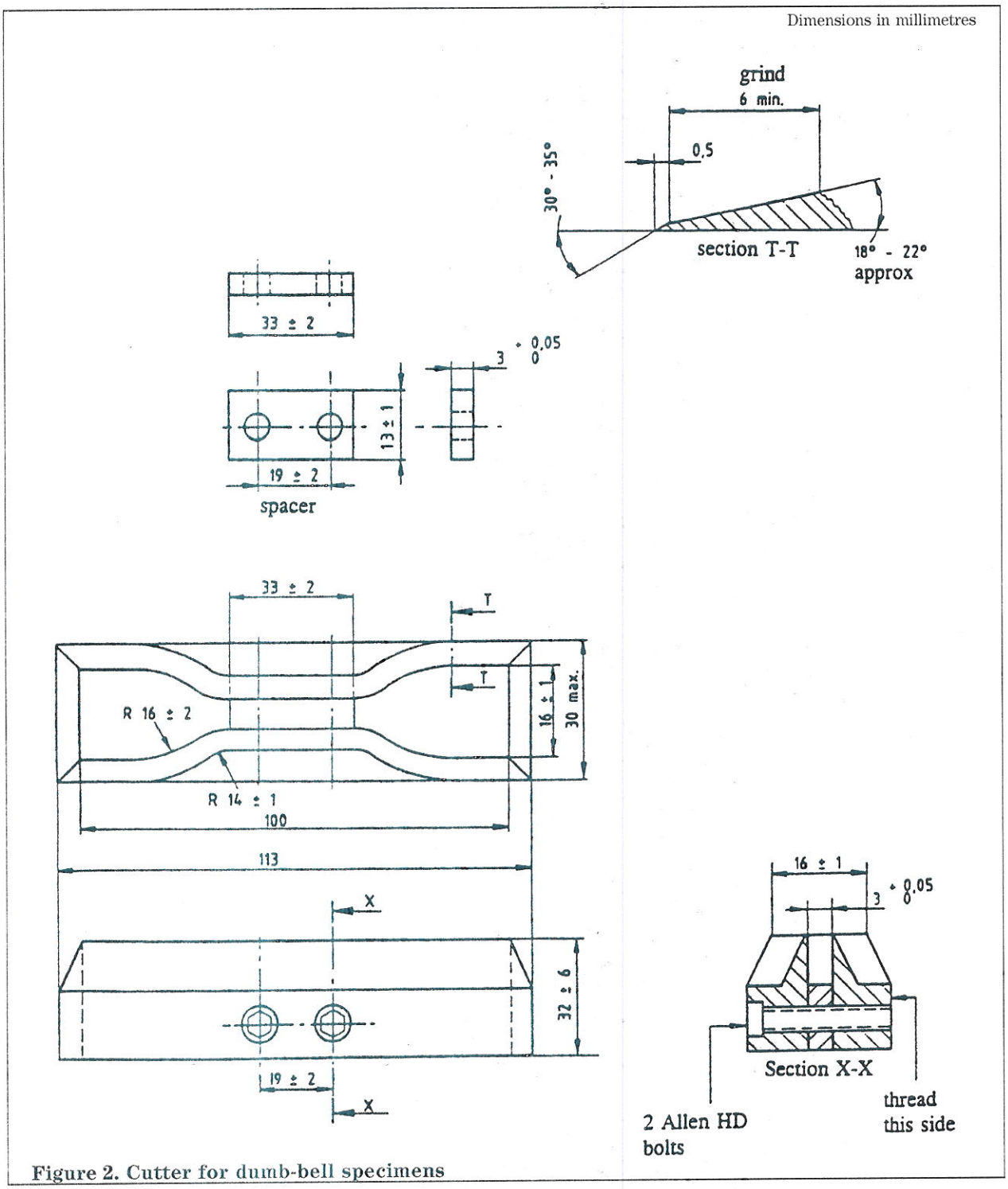

Figure 2. Cutter for dumb-bell specimens

6 Sampling, inspection level and AQL

For testing batches of gloves as described in clauses **4** and **5** for referee purposes, the sample size and allowable number of non-conforming gloves in the sample shall be determined from ISO 2859-1 using inspection level S2 with an AQL of 4.

7 Test report

The test report shall include at least the following information:

a) reference to this standard;
b) the type of glove and manufacturer's batch code;
c) name and address of the manufacturer or distributor and test laboratory;
d) date of testing;
e) test results.

Annex ZA (informative)

Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

This European Standard has been prepared under a mandate given to CEN/CENELEC by the European Commission and the European Free Trade Association and supports essential requirements of EU Directive 93/42/EEC.

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

The following clauses of this standard, as detailed in table ZA.1, are likely to support requirements of Directive 93/42/EEC.

Compliance with the clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table ZA.1: Correspondence between this European Standard and EU Directives

Clause/subclause of this European Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
4	1, 3, 5, 9.2	
5	1, 3 9.2	
5.2	9.2	
6	1, 3 9.2	
7	9.2	

List of references

See national foreword.

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: 0181 996 9000. Fax: 0181 996 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: 0181 996 7000. Fax: 0181 996 7001.

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 the Information Centre. Tel: 0181 996 7111. Fax: 0181 996 7048.

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: 0181 996 7002. Fax: 0181 996 7001.

Copyright

BSI
389 Chiswick High Road
London
W4 4AL