

BS EN ISO 15841:2014



BSI Standards Publication

Dentistry — Wires for use in orthodontics

bsi.

...making excellence a habit.™

National foreword

This British Standard is the UK implementation of EN ISO 15841:2014. It supersedes BS EN ISO 15841:2006 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/106/1, Dental restorative and orthodontic materials.

A list of organizations represented on this committee 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.

© The British Standards Institution 2014. Published by BSI Standards Limited 2014

ISBN 978 0 580 80712 1

ICS 11.060.10

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 31 August 2014.

Amendments issued since publication

Date	Text affected
------	---------------

English Version

Dentistry - Wires for use in orthodontics (ISO 15841:2014)

Médecine bucco-dentaire - Fils pour utilisation en
orthodontie (ISO 15841:2014)

Zahnheilkunde - Drähte für die Kieferorthopädie (ISO
15841:2014)

This European Standard was approved by CEN on 25 July 2014.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

This document (EN ISO 15841:2014) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee CEN/TC 55 "Dentistry" 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 February 2015, and conflicting national standards shall be withdrawn at the latest by February 2015.

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 EN ISO 15841:2006.

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.

Endorsement notice

The text of ISO 15841:2014 has been approved by CEN as EN ISO 15841:2014 without any modification.

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Classification	2
5 Requirements	3
5.1 General.....	3
5.2 Dimensions.....	3
5.3 Austenite finish temperature.....	3
5.4 Mechanical properties.....	3
5.5 Hazardous elements.....	3
6 Test methods	3
6.1 Sampling.....	3
6.2 Dimensions.....	3
6.3 Austenite-finish temperature.....	4
6.4 Mechanical tests.....	5
7 Packaging and labelling information to be provided to the user	8
7.1 General requirements.....	8
7.2 Packaging.....	8
7.3 Labelling.....	9
Bibliography	10

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

The committee responsible for this document is ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*.

This second edition of ISO 15841 cancels and replaces the first edition (ISO 15841:2006), which has been revised to include a reference to ASTM F2082.

Introduction

As with the first edition, the second edition of this International Standard has been developed to help clinicians compare the wires from different manufacturers and suppliers. In particular, it has been written as a result of the development of new test methods.

Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological hazards are not included in this International Standard. For the assessment of possible biological hazards, reference can be made to ISO 10993 and ISO 7405.

Dentistry — Wires for use in orthodontics

1 Scope

This International Standard specifies requirements and test methods for wires to be used in fixed and removable orthodontic appliances. It includes preformed orthodontic archwires but excludes springs and other preformed components.

This International Standard gives detailed requirements concerning the presentation of the physical and mechanical properties of orthodontic wires, the test methods by which they can be determined, and packaging and labelling information.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1942, *Dentistry — Vocabulary*

ISO 6892-1, *Metallic materials — Tensile testing — Part 1: Method of test at room temperature*

ASTM F2082, *Standard Test Method for Determination of Transformation Temperature of Nickel-Titanium Shape Memory Alloys by Bend and Free Recovery*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

3.1

austenite-finish temperature

T_{af}

temperature at which the metallurgical transformation from the low-temperature martensite phase to the high-temperature austenite phase is completed

3.2

force deflection rate

F_{Δ}

increment of load to produce a unit increment of deflection in the proportional region, expressed in N/mm (e.g. used in the bend test)

3.3

descriptor

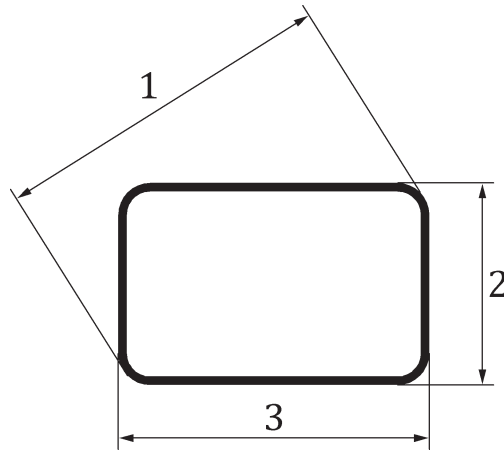
code to identify the nominal dimension(s) in thousandths of an inch without unit designation, in accordance with accepted orthodontic practice

3.4

diagonal

largest cross-sectional dimension of a rectangular wire

Note 1 to entry: See [Figure 1](#).



Key

- 1 diagonal
- 2 height
- 3 width

Figure 1 — Dimensions of cross section of a wire

**3.5
multistrand wire**

orthodontic wire fabricated from two or more individual strands of wire that may be twisted, braided or made into a co-axial wire

**3.6
offset bending force**

$F_{S(0,1)}$
force measured at a permanent deflection of 0,1 mm during loading in the bend test

**3.7
height**
smallest cross-sectional dimension of a rectangular wire

Note 1 to entry: See [Figure 1](#).

**3.8
width**
larger of the height and width dimensions of a rectangular wire

Note 1 to entry: See [Figure 1](#).

4 Classification

For the purposes of this document, wires are classified on the basis of their elastic behaviour.

- a) **Type 1 wires:** wires displaying linear elastic behaviour during unloading at temperatures up to 50 °C.
- b) **Type 2 wires:** wires displaying nonlinear elastic behaviour during unloading at temperatures up to 50 °C.

5 Requirements

5.1 General

The manufacturer shall declare the following properties, which, when tested in accordance with the test methods described in [Clause 6](#), shall be within the ranges stated by the manufacturer.

5.2 Dimensions

Each cross-sectional dimension (diameter, width, height and diagonal, as applicable) of the wire shall be stated to the nearest 0,01 mm. For multistrand wires, the dimensions shall be the internal dimensions of a tube that would just contain the wire.

5.3 Austenite finish temperature

For Type 2 wires, the austenite finish temperature shall be stated to the nearest 1 °C. Austenite-finish temperature shall be determined in accordance with either [6.3.1](#) or [6.3.2](#).

5.4 Mechanical properties

When a manufacturer states that different segments of an orthodontic wire have different mechanical properties, the results for each segment shall be tested separately and stated separately.

5.4.1 Type 1 wires

The modulus of elasticity, in gigapascals, 0,2 % proof strength, in megapascals, and percentage elongation after fracture when tested in accordance with [6.4.2](#), shall be stated.

The force deflection rate, in newtons per millimetre, and 0,1 mm offset bending force, in newtons, when tested in accordance with [6.4.3](#) shall be stated.

5.4.2 Type 2 wires

The force magnitudes measured during unloading at deflections of 3,0 mm, 2,0 mm, 1,0 mm and 0,5 mm and the permanent deflection after unloading, when tested in accordance with [6.4.3](#) shall be stated.

5.5 Hazardous elements

For the purposes of this International Standard, cadmium, beryllium, lead and nickel are designated to be hazardous elements and the manufacturer shall state the concentrations as a mass fraction expressed as a percentage.

6 Test methods

6.1 Sampling

Six specimens of a single product from one batch shall be procured for each test. Where the manufacturer recommends heat treatment prior to clinical use, that heat treatment shall be carried out according to the manufacturer's instructions, before testing.

6.2 Dimensions

Measurement shall be taken using callipers, micrometers, optical comparators or other devices with an accuracy of 0,005 mm.

Measurements shall be made on each dimension of each sample.

6.3 Austenite-finish temperature

6.3.1 Differential scanning calorimetry apparatus, calibrated to 1 °C

6.3.1.1 Procedure

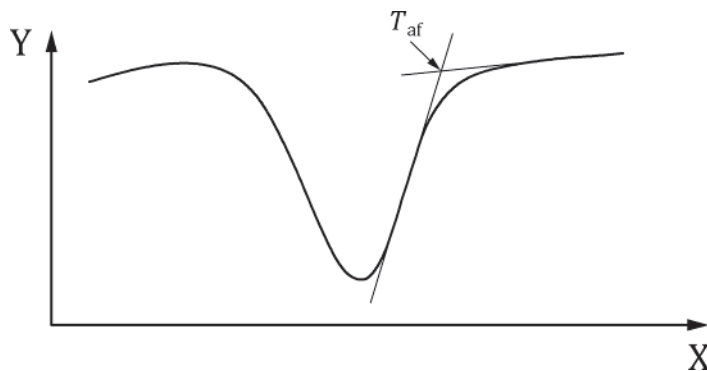
Determine the austenite-finish temperature by differential scanning calorimetry according to the instructions for the instrument.

A heating rate of (10 ± 2) °C/min shall be used.

Cut specimens to a length suitable for the test instrument.

6.3.1.2 Determination of austenite-finish temperature

From the curve obtained by differential scanning calorimetry (see [Figure 2](#)), the austenite-finish temperature shall be determined from the high temperature side of the valley, as the point of intersection between the tangent drawn at the inflection point and the asymptotic line to the adjacent baseline curve. The intersection of the tangent lines is determined as the austenite-finish temperature, T_{af} , and is reported in degrees Celsius.



Key

X temperature, in degrees Celsius

Y heat flow, in joules per second

Figure 2 — Differential scanning calorimetry curve and interpretation

6.3.2 Bend and free recovery, calibrated to 1 °C

6.3.2.1 Procedure

Determination of the austenite-finish temperature, T_{af} , from bend and free recovery, in accordance with ASTM F2082.

6.3.2.2 Determination of austenite-finish temperature

Determine the austenite-finish temperature, T_{af} , from the curve obtained by bend and free recovery, according to ASTM F2082 and report the result in degrees Celsius.

6.4 Mechanical tests

6.4.1 General

Samples for tensile or bend tests shall be straight. If the wire is delivered coiled, care shall be taken to straighten it. When samples are taken from preformed orthodontic archwires, the samples shall be cut from the straightest section of the archwire.

6.4.2 Tensile test

6.4.2.1 General

The tests shall be carried out in accordance with ISO 6892-1 to obtain the modulus of elasticity, 0,2 % proof strength and percentage elongation after fracture.

6.4.2.2 Apparatus

6.4.2.2.1 Tensile testing apparatus, calibrated for a crosshead rate and force in the range of 0,5 mm/min to 2,0 mm/min.

6.4.2.2.2 Micrometer or equivalent instrument, with an accuracy of 0,005 mm.

6.4.2.3 Procedure

6.4.2.3.1 The crosshead rate shall be in the range of 0,5 mm/min to 2,0 mm/min.

6.4.2.3.2 The original cross-sectional area, S_0 , shall be determined using a micrometer or equivalent instrument (6.4.2.2.2) with an accuracy of 0,005 mm. For products of circular cross-section, the original cross-sectional area may be calculated from the arithmetic mean of two measurements carried out in two perpendicular directions. The original cross-sectional area may also be determined from the mass of a known length and the material's density.

6.4.2.3.3 The original gauge length, L_0 , shall be taken as $(20 \pm 0,2)$ mm.

6.4.2.3.4 The distance between the grips of the machine shall be at least $(L_0 + 50)$ mm.

6.4.2.3.5 Determine the percentage elongation after fracture using a measuring device with 0,1 mm resolution.

6.4.2.3.6 Determine the modulus of elasticity from the slope of the linear portion of the force-deflection diagram.

6.4.2.3.7 Determine the proof strength from the stress-strain diagram at 0,2 % strain.

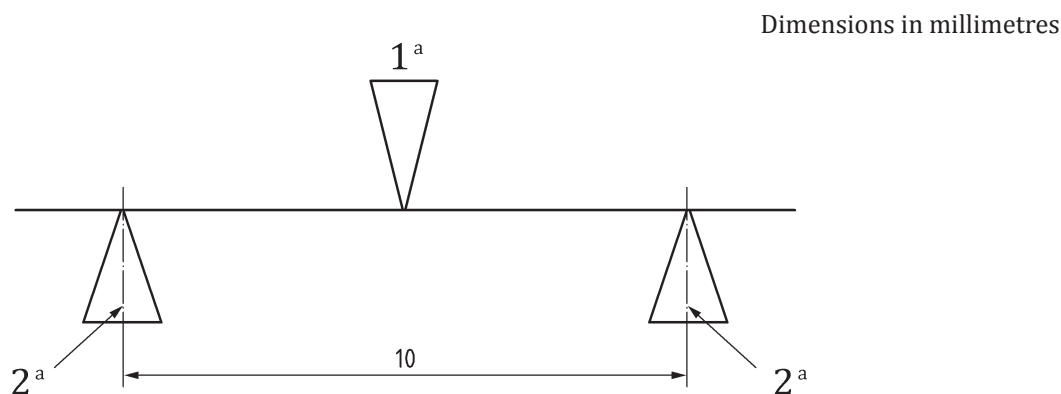
6.4.3 Bend test

6.4.3.1 Apparatus

6.4.3.1.1 Compression testing apparatus, calibrated for a crosshead rate in the range of 0,5 mm/min to 2,0 mm/min.

6.4.3.2 Procedure

- 6.4.3.2.1 The crosshead rate shall be $(1,25 \pm 0,75)$ mm/min.
- 6.4.3.2.2 Specimens shall be cut to a minimum length of 30 mm.
- 6.4.3.2.3 The wires shall be subjected to a symmetrical three-point bend test.
- 6.4.3.2.4 A span of wire 10 mm between supports shall be used (see [Figure 3](#)).
- 6.4.3.2.5 Deflection shall be carried out with a centrally-placed indenter.
- 6.4.3.2.6 The radii of fulcrum and indenter shall be $(0,10 \pm 0,05)$ mm.
- 6.4.3.2.7 Rectangular wires shall be tested in the direction of the height of the wire.



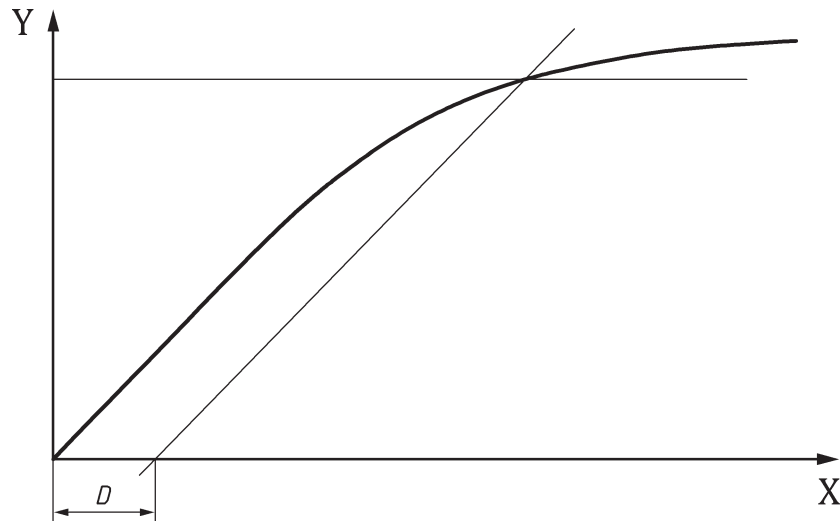
Key

- 1 indenter
- 2 fulcrum
- ^a The radii of fulcrum and indenter shall be $(0,10 \pm 0,05)$ mm.

Figure 3 — Three-point bend test

6.4.3.3 Procedure for Type 1 wires

- 6.4.3.3.1 Type 1 wires may be tested at room temperature (23 ± 2) °C.
- 6.4.3.3.2 The wire shall be deflected to a minimum permanent deflection of 0,1 mm.
- 6.4.3.3.3 The offset bending force is the force at a permanent deflection of 0,1 mm.
- 6.4.3.3.4 Force deflection rate is determined from the force-deflection diagram by calculating the slope of the line that is parallel to the linear portion of the curve at a deflection of 0,1 mm. See [Figure 4](#).



Key

- X deflection, in millimetres
- Y force, in newtons
- D permanent deflection of 0,1 mm

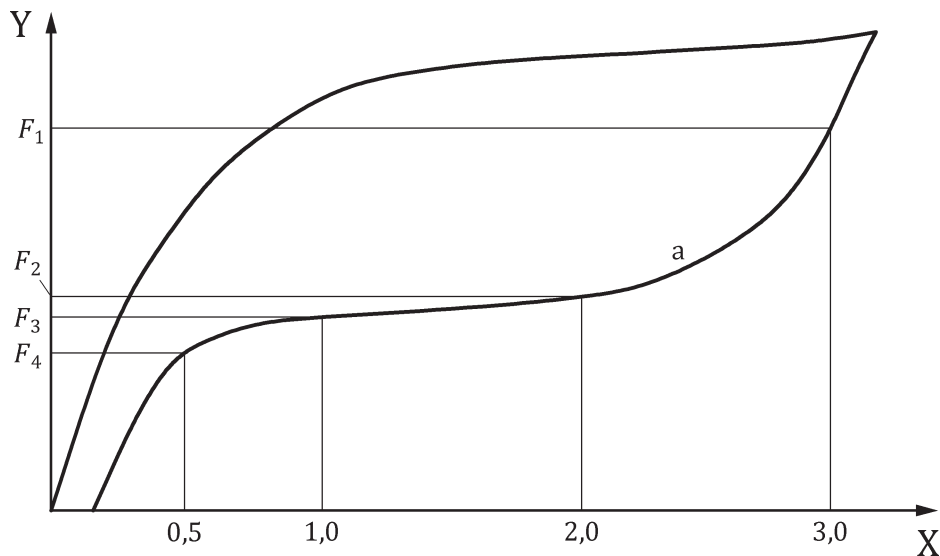
Figure 4 — Bend stiffness curve

6.4.3.4 Procedure for Type 2 wires

6.4.3.4.1 Type 2 wires shall be tested in the range (36 ± 1) °C.

6.4.3.4.2 The wire shall be deflected to 3,1 mm.

6.4.3.4.3 Bending force during unloading is determined from the force-deflection diagram by recording the force readings taken at deflections of 3,0 (F_1), 2,0 (F_2), 1,0 (F_3), and 0,5 (F_4) mm (see [Figure 5](#)).



Key

X deflection, in millimetres

Y force, in newtons

a Results are measured on the unloading curve (lower curve).

Figure 5 — Bend test curve

7 Packaging and labelling information to be provided to the user

7.1 General requirements

The manufacturer shall make the following readily available in the catalogue, packaging insert, labelling or other readily accessible means:

- a) the classification of the wire;
- b) the recommended heat-treating procedure for heat-treatable alloys;
- c) declaration of chemical composition: the range of composition of the alloy shall include all elements present at concentrations of 0,1 % by mass or greater, and the mass fractions of any hazardous elements as defined in [5.5](#);
- d) the range of each cross-sectional dimension determined in accordance with [5.2](#);
- e) the mechanical properties determined in accordance with [5.4](#);
- f) the austenite-finish temperature where applicable determined in accordance with [5.3](#).

NOTE Additional information may be included at the discretion of the manufacturer or as required by legislation.

7.2 Packaging

Adequate containment and protection from contamination during transit and storage shall be provided in accordance with acceptable commercial practice.

7.3 Labelling

Each package shall be labelled with at least the following information:

- a) name and address of the manufacturer and/or distributor;
- b) name or trade name of wire;
- c) dimensions of wire, in millimetres (additional use of a descriptor is permitted);
- d) lot number;
- e) the quantity of wires in number, length or weight;
- f) the intended use of the wire;
- g) a warning for products containing hazardous elements (where appropriate, this information should take the form of symbols).

Bibliography

- [1] ISO 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*
- [2] ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

British Standards Institution (BSI)

BSI is the national body responsible for preparing British Standards and other standards-related publications, information and services.

BSI is incorporated by Royal Charter. British Standards and other standardization products are published by BSI Standards Limited.

About us

We bring together business, industry, government, consumers, innovators and others to shape their combined experience and expertise into standards-based solutions.

The knowledge embodied in our standards has been carefully assembled in a dependable format and refined through our open consultation process. Organizations of all sizes and across all sectors choose standards to help them achieve their goals.

Information on standards

We can provide you with the knowledge that your organization needs to succeed. Find out more about British Standards by visiting our website at bsigroup.com/standards or contacting our Customer Services team or Knowledge Centre.

Buying standards

You can buy and download PDF versions of BSI publications, including British and adopted European and international standards, through our website at bsigroup.com/shop, where hard copies can also be purchased.

If you need international and foreign standards from other Standards Development Organizations, hard copies can be ordered from our Customer Services team.

Subscriptions

Our range of subscription services are designed to make using standards easier for you. For further information on our subscription products go to bsigroup.com/subscriptions.

With **British Standards Online (BSOL)** you'll have instant access to over 55,000 British and adopted European and international standards from your desktop. It's available 24/7 and is refreshed daily so you'll always be up to date.

You can keep in touch with standards developments and receive substantial discounts on the purchase price of standards, both in single copy and subscription format, by becoming a **BSI Subscribing Member**.

PLUS is an updating service exclusive to BSI Subscribing Members. You will automatically receive the latest hard copy of your standards when they're revised or replaced.

To find out more about becoming a BSI Subscribing Member and the benefits of membership, please visit bsigroup.com/shop.

With a **Multi-User Network Licence (MUNL)** you are able to host standards publications on your intranet. Licences can cover as few or as many users as you wish. With updates supplied as soon as they're available, you can be sure your documentation is current. For further information, email bsmusales@bsigroup.com.

BSI Group Headquarters

389 Chiswick High Road London W4 4AL UK

Revisions

Our British Standards and other publications are updated by amendment or revision.

We continually improve the quality of our products and services to benefit your business. If you find an inaccuracy or ambiguity within a British Standard or other BSI publication please inform the Knowledge Centre.

Copyright

All the data, software and documentation set out in all British Standards and other BSI publications are the property of and copyrighted by BSI, or some person or entity that owns copyright in the information used (such as the international standardization bodies) and has formally licensed such information to BSI for commercial publication and use. Except as permitted under the Copyright, Designs and Patents Act 1988 no extract may be reproduced, stored in a retrieval system or transmitted in any form or by any means – electronic, photocopying, recording or otherwise – without prior written permission from BSI. Details and advice can be obtained from the Copyright & Licensing Department.

Useful Contacts:

Customer Services

Tel: +44 845 086 9001

Email (orders): orders@bsigroup.com

Email (enquiries): cservices@bsigroup.com

Subscriptions

Tel: +44 845 086 9001

Email: subscriptions@bsigroup.com

Knowledge Centre

Tel: +44 20 8996 7004

Email: knowledgecentre@bsigroup.com

Copyright & Licensing

Tel: +44 20 8996 7070

Email: copyright@bsigroup.com



...making excellence a habit.™