BSI Standards Publication

Ophthalmic optics – Spectacle frames – Requirements and test methods

National foreword

This British Standard is the UK implementation of EN ISO 12870:2018. It is identical to ISO 12870:2016. It supersedes BS EN ISO 12870:2014, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/172, Ophthalmic optics.

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.

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31 March 2020	Annex ZA added

EUROPEAN STANDARD **EN ISO 12870**

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Supersedes EN ISO 12870:2014

English Version

Ophthalmic optics - Spectacle frames - Requirements and test methods (ISO 12870:2016)

Optique ophtalmique - Montures de lunettes - Exigences et méthodes d'essai (ISO 12870:2016)

Augenoptik - Brillenfassungen - Anforderungen und Prüfverfahren (ISO 12870:2016)

This European Standard was approved by CEN on 26 April 2018.

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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.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN ISO 12870:2018 E

European foreword

The text of ISO 12870:2016 has been prepared by Technical Committee ISO/TC 172 "Optics and photonics" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 12870:2018 by Technical Committee CEN/TC 170 "Ophthalmic optics" 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of an identical text or by endorsement, at the latest by November 2018, and conflicting national standards shall be withdrawn at the latest by November 2018.

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

This document supersedes EN ISO 12870:2014.

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.

Endorsement notice

The text of ISO 12870:2016 has been approved by CEN as EN ISO 12870:2018 without any modification.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard 'within the meaning of Annex ZA', the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — Correlation between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO
ISO 105-A02	—	ISO 105-A02:1993 + Cor.1:1997 + Cor.2:2005
ISO 105-B02	EN ISO 105-B02:2014	ISO 105-B02:2014
ISO 3696	EN ISO 3696:1995	ISO 3696:1987

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO
ISO 7998	EN ISO 7998:2005	ISO 7998:2005
ISO 8596	EN ISO 8596:2018	ISO 8596:2017
ISO 8624:2011	EN ISO 8624:2011 + A1:2015	ISO 8624:2011 + Amd.1:2015
ISO 11380	EN ISO 11380:1996	ISO 11380:1994
ISO 11381	EN ISO 11381:2016	ISO 11381:2016
ISO/TS 24348:2014	EN 16128:2011[a]	ISO/TS 24348:2014

[a] Note that EN 16128 has recently been revised and its most recent edition is now 2015. ISO/TS 24348:2014 will be amended to align with the text of EN 16128:2015.

Annex ZA
(informative)

Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's standardization request [M/023 concerning the development of European Standards related to medical devices] to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative 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.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 93/42/EEC [OJ L 169]

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
7.2	4.2.2, 4.2.3	This ER is covered only for certain specific aspects and substances which are mentioned in the indicated paragraphs. This ER is covered in respect of substances migrating to the wearer only. The requirement of 4.2.3 is the requirement set forth by Entry 27 of Annex XVII to REACH. With respect to testing 4.2.3 makes reference to EN 16128. See also explanations in Annex C.
7.3	4.6, 4.7, 4.8	Only the first part of this ER applies to spectacle frames, and this is covered only for certain specific aspects which are mentioned in the indicated paragraphs.

Essential Requirements of Directive 93/42/EEC	**Clause(s)/sub-clause(s) of this EN**	**Remarks/Notes**
7.5	4.2.2, 4.2.3, 4.2.4, 4.7, 4.9	1st paragraph of ER 7.5 is partially covered by the overall but not specific guidance in subclause 4.2.2. Specific guidance is given for nickel, in subclause 4.2.3. The requirement of 4.2.3 (i.e. 0,5 µg/cm²/week) is the requirement set forth by Entry 27 of Annex XVII to REACH. With respect to testing 4.2.3 makes reference to EN 16128. See also explanations in Annex C. 2nd and 3rd paragraph of ER 7.5 are not applicable to spectacle frames.
9.1	4.8	Only the first sentence of ER 9.1 is covered.
9.2	4.2.1, 4.6	From the 1st bullet point of ER 9.2, the dimensional and ergonomic features are applicable to spectacle frames and are covered by 4.2.1. Volume/pressure ratio is not applicable to spectacle frames. From the 2nd bullet point of ER 9.2, temperature is applicable to spectacle frames, and is covered by 4.6. Magnetic fields, external electrical influences, electrostatic discharge, pressure, variations in pressure and acceleration are not applicable to spectacle frames. The 3rd and 4th bullet points of ER 9.2 are not applicable.
9.3	4.9	—
13.3 a)	10.4	The statement in 10.4 is mandatory for the countries of the Community. It covers the authorized representative only (where applicable).
13.3 b)	9, 10.1, 10.5, 10.6	The ER is covered only in respect of the aspects detailed in the standard.
13.3 i)	10.1	The ER is covered only in respect of the aspects detailed in the standard.
13.3 j)	10.1, 10.5, 10.6	The ER is covered only in respect of the aspects detailed in the standard.
13.3 k)	10.1, 10.5, 10.6	The ER is covered only in respect of the aspects detailed in the standard.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this

standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.

Contents

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 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This fourth edition cancels and replaces the third edition (ISO 12870:2012), which has been technically revised with the following change:

— 8.8 and Annex C are now covered in more specific standards (ISO/TS 24348:2014 and EN 16128:2015, respectively) and are now included as appropriate reference to this International Standard (see 4.2.3 and Annex C).

INTERNATIONAL STANDARD ISO 12870:2016(E)

Ophthalmic optics — Spectacle frames — Requirements and test methods

1 Scope

This International Standard specifies fundamental requirements for unglazed spectacle frames designed for use with all prescription lenses. It is applicable to frames at the point of sale by the manufacturer or supplier to the retailer.

This International Standard is applicable to all spectacle frame types, including rimless mounts, semi-rimless mounts and folding spectacle frames. It is also applicable to spectacle frames made from natural organic materials.

NOTE See Annex A for recommendations on the design of spectacle frames.

This International Standard is not applicable to complete custom-made spectacle frames or to products designed specifically to provide personal eye protection.

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 105-A02, *Textiles — Tests for colour fastness — Part A02: Grey scale for assessing change in colour*

ISO 105-B02, *Textiles — Tests for colour fastness — Part B02: Colour fastness to artificial light: Xenon arc fading lamp test*

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 7998, *Ophthalmic optics — Spectacle frames — Lists of equivalent terms and vocabulary*

ISO 8596, *Ophthalmic optics — Visual acuity testing — Standard optotype and its presentation*

ISO 8624:2011, *Ophthalmic optics — Spectacle frames — Measuring system and terminology*

ISO 11380, *Optics and optical instruments — Ophthalmic optics — Formers*

ISO 11381, *Optics and optical instruments — Ophthalmic optics — Screw threads*

ISO/TS 24348:2014, *Ophthalmic optics — Spectacle frames — Method for the simulation of wear and detection of nickel release from metal and combination spectacle frames*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7998 and ISO 8624 and the following apply.

3.1
spectacle frame model
spectacle frame produced to a common design, using the same materials (but not necessarily the same pigmentation) and surface treatment