BRITISH STANDARD

BS EN 14139:2010

Ophthalmic optics — Specifications for ready-to-wear spectacles

ICS 11.040.70

National foreword

This British Standard is the UK implementation of EN 14139:2010. It supersedes BS EN 14139:2002 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/172/3, Spectacles.

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

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English Version

Ophthalmic optics - Specifications for ready-to-wear spectacles

Optique ophtalmique - Spécifications pour les lunettes prémontées

Augenoptik - Anforderungen an Fertigbrillen

This European Standard was approved by CEN on 13 May 2010.

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Foreword

This document (EN 14139:2010) has been prepared 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of an identical text or by endorsement, at the latest by December 2010, and conflicting national standards shall be withdrawn at the latest by December 2010.

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 14139:2002.

It has been adapted from ISO 16034:2002.

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 93/42/EEC, as amended by Directive 2007/47/EC.

For relationship with EU Directive 93/42/EEC as amended by Directive 2007/47/EC, see informative Annex ZA, which is an integral part of this document.

Significant technical changes from the previous edition of the document:

- clarification that the marking of ready-to-wear spectacles according to EN ISO 12870 is optional (note to subclause 5.1).

- amendment of requirements regarding the information to be provided by the manufacturer (subclause 5.2).

- the new edition of the standard is placed under EC Mandate (Directive 93/42/EEC on medical devices) and an Annex ZA was hence added.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

1 Scope

This European Standard specifies the minimum requirements for complete ready-to-wear spectacles. These are not intended for regular use without the approval of an eye-care professional.

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.

EN ISO 7998, *Ophthalmic optics — Spectacle frames — Lists of equivalent terms and vocabulary (ISO 7998:2005)*

EN ISO 8624, *Ophthalmic optics — Spectacle frames — Measuring system and terminology (ISO 8624:2002)*

EN ISO 8980-1, *Ophthalmic optics — Uncut finished spectacle lenses — Part 1: Specifications for single-vision and multifocal lenses (ISO 8980-1:2004)*

EN ISO 12870, *Ophthalmic optics — Spectacle frames — Requirements and test methods (ISO 12870:2004)*

EN ISO 13666, *Ophthalmic optics — Spectacle lenses — Vocabulary (ISO 13666:1998)*

EN ISO 14889, *Ophthalmic optics — Spectacle lenses — Fundamental requirements for uncut finished lenses (ISO 14889:2003)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN ISO 7998 and in EN ISO 13666 and the following apply.

3.1
ready-to-wear spectacles
spectacles intended for near vision and reading use only having or incorporating a pair of single vision lenses of equal positive spherical power in which the glazing has not been carried out in direct response to a written prescription by a qualified practitioner

NOTE The term "ready-to-wear spectacles“ as understood by this European Standard is restricted to spectacles having or incorporating single vision lenses. The rationale for this restriction is that spectacle lenses other than single vision lenses (e.g. bifocal, multifocal, progressive-power lenses) are not recommended for use in ready-to-wear spectacles due to the need of a qualified practitioner’s prescription and dispensing for such lenses.

4 Performance requirements

4.1 General

The tolerances shall apply at a temperature of 23 °C ± 5 °C.

4.2 General requirements

The spectacle lenses of ready-to-wear spectacles shall fulfil the general requirements of EN ISO 14889.

The frame of ready-to-wear spectacles shall fulfil the requirements of EN ISO 12870.

The glazing of spectacle lenses shall be verified by the lens retention test as specified in EN ISO 12870.

The spectacle lenses shall be securely held in position so that movement or rotation in the frame cannot occur under any condition of intended use.

4.3 Optical power range

The lenses for ready-to-wear spectacles shall have equal nominal spherical power within the range from +1,00 to +3,50 dioptres.

4.4 Optical power tolerances

Tolerances to be applied to the values declared by the manufacturer shall comply with EN ISO 8980-1.

4.5 Reference points and prismatic power tolerances

4.5.1 Design reference points

— Horizontal: The design reference points are specified by the manufacturer and are spaced symmetrically with respect to the vertical symmetry axis of the frame according to EN ISO 8624.

— Vertical: The design reference points may be specified by the manufacturer and shall be at the same height for each lens.

4.5.2 Prismatic power tolerances

The deviation of prismatic power (horizontal: per lens; vertical: difference between lenses) measured at the design reference points specified by the manufacturer, shall not exceed the values given in Table 1.

Table 1 — Prismatic tolerances

Horizontal tolerance	0,33 cm/m absolute each lens
Vertical tolerance	0,33 cm/m imbalance between lenses

5 Marking on the spectacles, indications on packaging, instruction for use

5.1 Marking

Spectacles shall be permanently marked with the following minimum information:

a) name or trade mark of manufacturer or distributor;

b) manufacturer's declared spherical power, in dioptres.

NOTE Additional marking of ready-to-wear spectacles according to EN ISO 12870 is optional.

5.2 Indications on packaging and warnings

Manufacturer's declared centration distance, in mm, shall be marked on the frame or on the hang tag or applied sticker.

Warning of the unsuitability for driving or road use shall be indicated by the symbol given in Figure 1.

Figure 1 — Symbol "not suitable for driving and road use"

A legible notice is required in the national language of the intended destination in the form of an affixed label or swing tag, as follows:

WARNING

- For near vision and reading use only
- Only regular eye-care professional eye examinations can determine your visual needs and eye health
- Not for driving or vehicle operation
- Not for distance vision
- Not for use as eye protection

The name and address of the manufacturer shall be marked on the frame or be given on the hang tag or applied sticker or packaging or information provided with the device. For devices imported into the Community, the name and address of the authorized representative in the Community shall be marked on the frame or be given on the hang tag or applied sticker or packaging or information provided with the device.

If the manufacturer or supplier claims compliance with this European Standard, its number and year shall be included either on the packaging or in the available literature.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on 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 on 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

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4.2	1, 2, 3, 4, 6, 7.1, 7.2, 7.3, 7.5, 9.1, 9.2, 9.3	These ERs are covered by normative reference to harmonized EN ISO 12870 and harmonized EN ISO 14889. ER 6 a) (clinical evaluation): This ER is implicitly covered via the normative reference to EN ISO 14889:2009 that will be revised with the intention to explicitly address it therein, and is partially covered in EN ISO 12870:2009 (this standard is under revision to cover this requirement). ER 7.5 This ER is only partially addressed in EN ISO 12870:2009 (this standard is under revision to cover this requirement).
4.3	1, 3	
4.4, 4.5	3, 7.1	
5.1, 5.2	13.1, 13.2, 13.3	

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

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