Draft for Public Comment

Form 36

DPC: 19/30380310 DC

BSI Group Headquarters

389 Chiswick High Road London W4 4AL

Tel: +44 (0)20 8996 9000
Fax: +44 (0)20 8996 7400
www.bsigroup.com

Date: 09 October 2019
Origin: European

Latest date for receipt of comments: 18 November 2019

Project No. 2018/02080

Responsible committee: PH/2/2 Industrial eye protectors

Interested committees:

Title: Draft BS EN ISO 12609-1 Eye and face protection against intense light sources used on humans and animals for cosmetic and medical applications. Part 1: Specification for products.

Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard

i) has any issues related to 3rd party IPR, patent or copyright
ii) affects other national standard(s)
iii) requires additional national guidance or information

WARNING: THIS IS A DRAFT AND MUST NOT BE REGARDED OR USED AS A BRITISH STANDARD. THIS DRAFT IS NOT CURRENT BEYOND 18 November 2019

This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. No acknowledgement will normally be sent. **See overleaf for information on the submission of comments.**

No copying is allowed, in any form, without prior written permission from BSI except as permitted under the Copyright, Designs and Patent Act 1988 or for circulation within a nominating organization for briefing purposes. Electronic circulation is limited to dissemination by e-mail within such an organization by committee members.

Further copies of this draft may be purchased from BSI Shop http://shop.bsigroup.com or from BSI Customer Services, Tel: +44(0) 20 8996 9001 or email cservices@bsigroup.com. British, International and foreign standards are also available from BSI Customer Services.

Information on the co-operating organizations represented on the committees referenced above may be obtained from https://standardsdevelopment.bsigroup.com/.

Responsible Committee Secretary: Ms Michelle Ravey (BSI)
Direct tel: 02089967032
E-mail: michelle.ravey@bsigroup.com

Documents
Document Sharing Hub
Full document details: 19/30380310 DC

Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at **https://standardsdevelopment.bsigroup.com/**. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx

1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex **(e.g. 3.1)**	Paragraph/Figure/ Table/Note	**Type of comment**	**Commend (justification for change) by the MB**	**Proposed change by the MB**	**Secretariat observations on each comment submitted**
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	

Documents
Document Sharing Hub

Full document details: 19/30380310 DC

DRAFT INTERNATIONAL STANDARD

ISO/DIS 12609-1

ISO/TC **94**/SC **6**

Secretariat: **BSI**

Voting begins on:
2019-09-25

Voting terminates on:
2019-12-18

Eye and face protection against intense light sources used on humans and animals for cosmetic and medical applications —

Part 1:
Specification for products

Protection des yeux et du visage contre les sources lumineuses intenses utilisées sur les animaux et les humains pour des applications médicales et cosmétiques —

Partie 1: Spécifications des produits

ICS: 13.340.20

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENT AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 12609-1:2019(E)

Documents
Document Sharing Hub

© ISO 2019

Full document details: 19/30380310 DC

COPYRIGHT PROTECTED DOCUMENT

© ISO 2019

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

© ISO 2019 – All rights reserved

Documents
Document Sharing Hub

Full document details: 19/30380310 DC

Contents

Page

Foreword ... **iv**

1 Scope ... **1**

2 Normative references ... **1**

3 Terms and definitions ... **2**

4 General requirements for ILS eye protectors ... **2**
4.1 Ambient temperatures ... 2
4.2 Physiological compatibility ... 2
4.3 Construction and adjustment ... 3
4.4 Cleaning and/or disinfection ... 3
4.5 Headform(s) ... 3
4.6 Mandatory and optional requirements ... 3

5 Transmittance ... **3**
5.1 General ... 3
5.2 Luminous and spectral transmittance for F-scale numbers ... 3
5.3 Luminous and spectral transmittance for B-scale numbers ... 4
5.4 Uniformity of luminous transmittance and transmittance matching ... 4

6 Colour neutrality (Optional requirement) ... **5**

7 ILS eye protectors with autodarkening filters ... **5**
7.1 General ... 5
7.2 Transmittance ... 5
7.3 Angular dependence of luminous transmittance ... 5
7.4 Switching time ... 6

8 Construction of ILS eye protectors ... **6**
8.1 Area to be protected from ILS radiation ... 6
8.2 Frames and lateral protection ... 7
8.3 Material and surface quality ... 7
8.4 Field of view ... 7
8.5 Optical properties ... 8
8.5.1 Spherical and cylindrical power ... 8
8.5.2 Spatial deviation ... 8
8.5.3 Prismatic power of unmounted plano filters covering one eye ... 8
8.5.4 Prism imbalance for mounted filters and one-piece protectors ... 8
8.5.5 Narrow angle scatter ... 9
8.6 Resistance to ignition ... 9
8.7 Resistance to UV radiation ... 9
8.8 Resistance to thermal exposure ... 9
8.9 Basic Impact Level of complete ILS eye protectors ... 9
8.9.1 Complete protector ... 9
8.9.2 Failure criteria ... 10
8.9.3 ILS eye protectors with inserts to carry prescription lenses ... 10

9 Marking ... **10**
9.1 General ... 10
9.2 Mandatory markings ... 11

10 Information to be supplied by the manufacturer ... **11**

Annex ZA (informative) **Relationship between this European Standard and the essential requirements of Regulation 2016/425 aimed to be covered** ... **13**

Bibliography ... **15**

© ISO 2019 – All rights reserved

Documents
Document Sharing Hub
Full document details: 19/30380310 DC

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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 94 *Personal safety – Personal protective equipment*, Subcommittee SC 6, *Eye and face protection.*

This second edition cancels and replaces the first edition (ISO 12609-1:2013) which has been technically revised.

The main changes compared to the previous edition are as follows:

— Alignment to ISO 16321 and ISO 18526 series.

A list of all parts in the ISO 12609 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

© ISO 2019 – All rights reserved
Documents
Document Sharing Hub
Full document details: 19/30380310 DC

Eye and face protection against intense light sources used on humans and animals for cosmetic and medical applications —

Part 1:
Specification for products

1 Scope

This document specifies general requirements for operators' eye protectors for intense light source (ILS) equipment used on humans and animals for cosmetic and medical applications against excessive exposure to optical radiation in the spectral range 250 nm to 3 000 nm, with the exception of laser radiation.

This document is applicable to devices intended for patient protection during ILS procedures except for treatment in periorbital area. For the guidance on patient eye protection during ILS procedures, see ISO/TR 22463.

Guidance on use and selection of ILS eye protectors – see ISO 12609-2.

This document does not apply to:

— laser protectors, for which ISO 19818 applies;

— protectors for medically prescribed applications (not occupational); e.g. eye protection for severe dry eye, tints prescribed for medical conditions;

— protectors specifically intended for protection against only solar radiation and used in non-occupational environments for which the ISO 12312 series applies; protectors used with tanning equipment;

— protectors intended to protect against ionizing radiation, e.g. X-rays, for which IEC 61331-3 applies.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 4007, *Personal protective equipment — Eye and face protection — Vocabulary*

ISO/FDIS 16321-1, — *Eye and face protection for occupational use — Part 1: General requirements*

ISO/FDIS 18526-1, — *Eye and face protection —Test methods — Part 1: Geometrical optical properties*

ISO/FDIS 18526-2, — *Eye and face protection — Test methods — Part 2: Physical optical properties*

ISO/FDIS 18526-3, — *Eye and face protection — Test methods — Part 3: Physical and mechanical properties*

ISO/FDIS 18526-4, — *Eye and face protection — Test methods — Part 4: Headforms*

© ISO 2019 – All rights reserved

Documents
Document Sharing Hub
Full document details: 19/30380310 DC