BS EN ISO 11978:2014

BSI Standards Publication

Ophthalmic optics — Contact lenses and contact lens care products — Labelling

bsi.

...making excellence a habit.™

Document Sharing Hub

Full document details: BS EN ISO 11978:2014

National foreword

This British Standard is the UK implementation of EN ISO 11978:2014. It supersedes BS EN ISO 11978:2000 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/172/9, Contact lenses and contact lens care products.

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 79988 4

ICS 11.040.70

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 October 2014.

Amendments issued since publication

Date	Text affected

Documents
Document Sharing Hub

Full document details: BS EN ISO 11978:2014

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11978

October 2014

ICS 11.040.70

English Version

Ophthalmic optics - Contact lenses and contact lens care products - Labelling (ISO 11978:2014)

Optique ophtalmique - Lentilles de contact et produits d'entretien des lentilles de contact - Étiquetage (ISO 11978:2014)

Einführendes Element - Haupt-Element - Ergänzendes Element (ISO 11978:2014)

This European Standard was approved by CEN on 21 June 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

© 2014 CEN All rights of exploitation in any form and by any means reserved worldwide for CEN national Members.

Ref. No. EN ISO 11978:2014 E

Documents
Document Sharing Hub

Full document details: BS EN ISO 11978:2014

Foreword

This document (EN ISO 11978:2014) has been prepared by Technical Committee ISO/TC 172 “Optics and photonics” in collaboration with 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 April 2015, and conflicting national standards shall be withdrawn at the latest by April 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 11978:2000.

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 11978:2014 has been approved by CEN as EN ISO 11978:2014 without any modification.

Documents
Document Sharing Hub

Full document details: BS EN ISO 11978:2014

Contents

Page

Foreword ..... **iv**
Introduction ..... **v**
1 Scope **1**
2 Normative references **1**
3 Terms and definitions **1**
4 Labelling requirements **1**
4.1 General 1
4.2 Contact lenses 1
4.3 Contact lens care products 4
Bibliography **7**

© ISO 2014 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS EN ISO 11978:2014

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 second edition cancels and replaces the first edition (ISO 11978:2000), which has been technically revised.

© ISO 2014 – All rights reserved
Documents
Document Sharing Hub
Full document details: BS EN ISO 11978:2014