SLOVENSKI STANDARD
SIST EN ISO 11978:2000

01-november-2000

Očesna optika - Kontaktne leče in izdelki za vzdrževanje kontaktnih leč - Informacije proizvajalca (ISO 11978:2000)

Ophtalmic optics - Contact lenses and contact lens care products - Information supplied by the manufacturer (ISO 11978:2000)

Augenoptik - Kontaktlinsen und Kontaktlinsenpflegemittel - Herstellerinformationen (ISO 11978:2000)

Optique ophtalmique - Lentilles de contact et produits d'entretien des lentilles de contact - Informations a fournir par le fabricant (ISO 11978:2000)

Ta slovenski standard je istoveten z: **EN ISO 11978:2000**

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

SIST EN ISO 11978:2000 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 11978

March 2000

ICS 11.040.70

English version

Ophtalmic optics - Contact lenses and contact lens care products - Information supplied by the manufacturer (ISO 11978:2000)

Optique ophtalmique - Lentilles de contact et produits d'entretien des lentilles de contact - Informations à fournir par le fabricant (ISO 11978:2000)

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This European Standard was approved by CEN on 15 March 2000.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN ISO 11978:2000 E

Foreword

The text of the International Standard ISO 11978:2000 has been prepared by Technical Committee ISO/TC 172 " Optics and optical instruments" 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 September 2000, and conflicting national standards shall be withdrawn at the latest by September 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

NOTE FROM CEN/CS: The foreword is susceptible to be amended on reception of the German language version. The confirmed or amended foreword, and when appropriate, the normative annex ZA for the references to international publications with their relevant European publications will be circulated with the German version.

Endorsement notice

The text of the International Standard ISO 11978:2000 was approved by CEN as a European Standard without any modification.

INTERNATIONAL STANDARD

ISO 11978

First edition
2000-03-15

Ophthalmic optics — Contact lenses and contact lens care products — Information supplied by the manufacturer

Optique ophtalmique — Lentilles de contact et produits d'entretien des lentilles de contact — Informations à fournir par le fabricant

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Contents

Page

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

International Standard ISO 11978 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

Introduction

This International Standard attempts to harmonize requirements, whenever possible, for labelling of contact lenses and contact lens care products with national laws, regulations or guidelines that may exist in countries throughout the world. Where national laws and labelling requirements exist in countries for medical devices, they are often developed by legislative bodies or regulatory authorities independently from the development process for International Standards. Therefore, labelling requirements established by an individual country cannot always be readily integrated into International Standards.

The information given in this International Standard provides a suitable framework for developing labelling for contact lenses and contact lens care products. Conformance to the elements herein should be sufficient for developing appropriate labelling for countries without existing laws or regulations for medical device labelling. However, conformance with the elements of this International Standard may not be sufficient for full compliance with additional labelling requirements mandated by an individual country. Where national laws or regulations mandate additional labelling requirements or conflict with elements of this International Standard, the national law or regulation should be followed and should take precedence over the elements of this voluntary International Standard.

Manufacturers should familiarize themselves with the labelling requirements, if any, of the countries chosen for marketing of their products. Failure to comply with labelling requirements of a specific country could result in serious consequences for a manufacturer that could otherwise have been avoided. Conformance with the elements of this International Standard should minimize, but may not necessarily eliminate, the risks for developing labelling that could seriously violate or conflict with specific requirements mandated by the laws and regulations of an individual country.