Ophthalmic optics - Contact lenses and contact lens care products - Labelling (ISO 11978:2017)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 11978:2017 sisaldab Euroopa standardi EN ISO 11978:2017 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 11978:2017 consists of the English text of the European standard EN ISO 11978:2017.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 13.09.2017.	Date of Availability of the European standard is 13.09.2017.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11978

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English Version

Ophthalmic optics - Contact lenses and contact lens care products - Labelling (ISO 11978:2017)

Optique ophtalmique - Lentilles de contact et produits d'entretien des lentilles de contact - Étiquetage (ISO 11978:2017)

This European Standard was approved by CEN on 8 September 2017.

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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.

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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

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European foreword

This document (EN ISO 11978:2017) 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 March 2018, and conflicting national standards shall be withdrawn at the latest by March 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 11978:2014.

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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 11978:2017 has been approved by CEN as EN ISO 11978:2017 without any modification.

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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 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments.*

This third edition cancels and replaces the second edition (ISO 11978:2014), of which it constitutes a minor revision.

The following change has been done:

In 4.1, paragraph 3

"All symbols and written information shall be legible under an illumination of 215 lx with visual acuity of 20/30 (Visus 0,67)."

has been replaced with

"All symbols and written information shall be a minimum of 0,7 mm in height and be legible at a reading distance of 30 cm under the illumination of 215 lx, except for Trademarks and any manufacturing part numbers."

Introduction

This document attempts to harmonize requirements, whenever possible, for labelling of contact lenses and contact lens care products with national laws, regulations, or guidelines that might 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 document provides a suitable framework for developing labelling for contact lenses and contact lens care products. Conformance to the elements herein is intended to be sufficient for developing appropriate labelling for countries without existing laws or regulations for medical device labelling. However, conformance with the elements of this document might 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 document, the national law or regulation is intended to be followed and is intended to take precedence over the elements of this voluntary document.

The manufacturer should provide more information to the contact lens professional upon request.

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

1 Scope

This document specifies the information to be provided by the manufacturer of contact lenses and contact lens care products to ensure the correct and safe use of these devices and their accessories by both types of user of contact lenses: the eye care professional and the contact lens wearer.

This document does not specify the format in which such information shall be provided.

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 15223–1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 18369–1, *Ophthalmic optics — Contact lenses — Part 1: Vocabulary, classification system and recommendations for labelling specifications*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18369–1 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

4 Labelling requirements

4.1 General

Where practicable and possible, the information supplied by the manufacturer shall be provided in the language of the country in which the device is distributed. Where appropriate, this information should take the form of symbols. Symbols used shall conform to ISO 15223–1. Where a symbol is not described in ISO 15223–1, it shall be described in the documentation supplied with the device.

Provided the minimum essential requirements are fulfilled, the manufacturer may use his discretion as to the format in which the information is provided, e.g. product-specific information either on the packaging for each unit or on the sales packaging, or in separated leaflets, brochures, booklets, or generic handling guides. These may be supplied as hard copy, electronic format, video, etc.

All symbols and written information shall be a minimum of 0,7 mm in height and be legible at a reading distance of 30 cm under the illumination of 215 lx, except for Trademarks and any manufacturing part numbers.