

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 11978:2014 sisaldab Euroopa standardi EN ISO 11978:2014 inglisekeelset teksti.	This Estonian standard EVS-EN ISO 11978:2014 consists of the English text of the European standard EN ISO 11978:2014.
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.
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ICS 11.040.70

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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)

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

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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of an identical text or by endorsement, at the latest by April 2015, and conflicting national standards shall be withdrawn at the latest by April 2015.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.

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Endorsement notice

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

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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 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 International Standard 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 International Standard 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 International Standard, the national law or regulation is intended to be followed and is intended to take precedence over the elements of this voluntary International Standard.

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 International Standard 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 users of contact lenses: the eye care professional and the contact lens wearer.

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

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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.

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 legible under an illumination of 215 lx with visual acuity of 20/30 (Visus 0,67).

4.2 Contact lenses

The labelling shall include at least the following (indicated in [Table 1](#) by an “X”), exceptions as noted.