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

Optique ophtalmique — Lentilles de contact et produits d'entretien des lentilles de contact — Étiquetage

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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).

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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."

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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.

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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.

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