INTERNATIONAL STANDARD

ISO 11978

Second edition
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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

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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.

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.

Table 1 — Labelling requirements for contact lenses

No.	Content	Label		Instructions for use	Comments
		Primary container	Secondary packaging		
1	Name or trade name and address of manufacturer[c]	X[a]	X	X	
2	Detailed requirements for the user to identify the device and the contents of the packaging, such as:				
a)	product identification and/or material name;	X	X	X	
b)	contact lens parameters;	X	X		
c)	number of contact lenses;	X[a]	X		
d)	packaging solution (e.g. phosphate-buffered saline solution) and identification of any preservative if present	X[a]	X	X	In exceptional cases, if the size of the primary container does not allow information regarding composition of storage solution, this information may be incorporated in the "Instructions for use".
3	The word "Sterile" together with method of sterilization	X	X	X	If applicable
4	Lot number prefixed by the word "LOT" or the symbol for "LOT"	X	X		
5	Expiry date	X	X		
6	The statement "For single use only"[d]	X[a]	X	X	If applicable
7	The statement "Custom made device"	X[a]	X	X	If applicable
8	Intended use or application			X	
9	The indication that the device is exclusively for use in a clinical investigation according to applicable regulations	X[a]	X	X	If applicable
10	Any special storage and/or handling conditions (e.g. Do not freeze.); any special operating instructions (e.g. Do not use if tamper-evident seal is damaged.)	X[a]	X	X	
11	The statement "Attention: See instructions for use." or the recognized symbol (see ISO 15223-1:2012, 5.4.3)	X[a]	X		
12	Replacement frequency, e.g. daily disposable, weekly disposable, or monthly disposable		X[b]	X	If applicable

[a] If contact lenses are not supplied with a secondary packaging, the required information shall be given on the primary container label.

[b] If the size of the secondary packaging does not allow the above information to be displayed, the relevant information shall appear on the "Instructions for use" leaflet.

[c] In those markets that require name and address of an authorized representative, this information shall be included.

[d] For the countries of the European Union, EU Directive 93/42/EEC stipulates that "A manufacturer's indication of single use must be consistent across the Community". Note that for contact lenses, "single use" implies a single wearing period the maximum duration of which will be specified by the manufacturer.

Table 1 *(continued)*

No.	Content	Label		Instructions for use	Comments
		Primary container	Secondary packaging		
13	Schedule for wear, e.g. daily wear and/or extended wear, as applicable			X	
14	Recommended and, if relevant, contraindicated care regimens			X	
15	Date of issue or the latest revision of the instruction for use			X	
16	Contraindications, warnings, and precautions or any other information deemed necessary by the manufacturer for the safe use of his contact lenses				
a)	Possible or known adverse reactions and side effects, and instructions to the wearer on the action to be taken if a problem occurs			X	
b)	Recommendations to follow the eye care professional's instructions for duration of use of the contact lens(es) on a daily basis, follow-up visits, and emergency procedures			X	
c)	Any directions or information necessary for the safe use of contact lenses if they have not been worn for a length of time			X	
d)	The information that contact lenses should be removed immediately after contact with noxious vapour, e.g. chemical or hazardous substances, or hazardous environment with ocular impact			X	
e)	The information that direct exposure of contact lenses to non-sterile water (e.g. tap water, whirlpool bath, swimming, participating in water sports) increases the risk of microbial infection			X	
f)	The information that the use of non-sterile water (e.g. tap water) in the handling of contact lenses and contact lens cases increases the risk of serious microbial infection			X	
g)	Instructions on cleaning and maintenance of contact lenses and contact lens cases			X	

[a] If contact lenses are not supplied with a secondary packaging, the required information shall be given on the primary container label.

[b] If the size of the secondary packaging does not allow the above information to be displayed, the relevant information shall appear on the "Instructions for use" leaflet.

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