INTERNATIONAL STANDARD

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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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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.

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

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 user 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 normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 8320-1:—[1)], *Contact lenses and contact lens care products — Vocabulary — Part 1: Contact lenses*.

ISO 8320-2:—[1)], *Contact lenses and contact lens care products — Vocabulary — Part 2: Contact lens care products.*

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 8320-1 and ISO 8320-2 and the following apply.

3.1
contact lens care product
contact lens accessory intended for use in maintaining the safety and performance of a contact lens after opening and removal of the contact lens from its original shipping package

NOTE This definition includes all devices recommended for use in the management of contact lens hygiene, for hydrating contact lenses, or for alleviating discomfort of contact lens wear by physical means.

[ISO 14534:1997]

3.2
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging and labelling of a medical device before it is placed on the market on his own behalf, regardless of whether these operations are carried out by that person himself or on his behalf by a third party

1) To be published.

3.3
information supplied by the manufacturer
details on the label and in the instructions for use of a medical device

4 Contact lens information supplied by the manufacturer

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 contact lens is distributed. Where appropriate, this information should take the form of symbols. Any symbol used shall conform to applicable standards. Where no standards exist, the symbols shall be described in the documentation supplied with the device.

Provided the minimum essential requirements are fulfilled (see 4.2 and 4.3), 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 separate leaflets, brochures, booklets or generic handling guides. These may be supplied as hard copy, electronic format, video, etc.

4.2 Label

4.2.1 The primary container and/or the secondary packaging shall include at least the following:

NOTE For labelling of contact lenses supplied in blister packs, see 4.2.3.

a) name or trade name and address of manufacturer;

b) details strictly necessary for the user to identify the device and the contents of the packaging, for example

1) product name and/or material name,

2) contact lens parameters,

3) number of contact lenses,

4) character of storage solution (e.g. phosphate-buffered saline solution) and identification of any preservative if present;

NOTE In exceptional cases, if the size of the primary packaging does not allow information regarding composition of storage solution this information may be incorporated in the “Instructions for use”.

c) if applicable, the word “Sterile” together with method of sterilization;

d) lot number prefixed by the word “Lot”;

e) expiry date;

f) if applicable, for “For single use only”;

g) if applicable, the statement “Custom made device”;

h) if applicable, the statement “Exclusively for clinical investigations”;

i) the instructions for use or, where appropriate, the words “Attention: See Instructions for Use”.

Where applicable and where space permits, the label shall also include any special storage and/or handling conditions; any special operating instructions; any warnings and/or precautions to take.

4.2.2 The secondary packaging shall include at least the items given in 4.2.1 plus the following:

a) the words “Attention: See Instructions for Use”, together with any special storage and/or handling conditions, e.g. do not freeze;

b) any special operating instructions, e.g. “Do not use if tamper-evident seal is damaged”;

c) any warnings and/or precautions to take;

d) daily wear products to be labelled: “For daily wear only”;

e) replacement schedule, if applicable.

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.

4.2.3 For contact lenses supplied in blister packs (either individually or in blister strips), the following minimum information shall be included on each blister for identification purposes:

a) lot number;

b) contact lens parameters;

c) expiry date.

4.3 Instructions for use

At least the following information shall be provided by the manufacturer to the users. It is recommended to give this information in written form. The manufacturer shall request the eye care professional to hand these written instructions to the patient/end user.

a) Name or trade name and address of the manufacturer;

b) details strictly necessary for the user to identify the contact lens and the contents of the packaging, for example

   1) product name and/or material name,

   2) composition of storage solution and identification of any preservative, if present;

c) if applicable, the information that the contact lens was/is supplied sterile, including method of sterilization;

d) intended use or application;

e) schedule for wear, e.g. daily wear/extended wear as applicable;

f) recommended replacement schedule;

g) recommended and, if relevant, contraindicated care regimens;

h) contraindications, warnings and precautions or any other information deemed necessary by the manufacturer for the safe use of his contact lenses;

i) possible or known adverse reactions and side effects, and instructions to the wearer on the action to be taken if a problem occurs;

j) recommendations to follow the eye care professional’s instructions for duration of use of the contact lens(es) on a daily basis, for follow-up visits, and for emergency procedures;