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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](http://www.iso.org/directives)).

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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.

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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.