

**BUREAU OF INDIAN STANDARDS**

**DRAFT FOR COMMENTS ONLY**

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**भारतीय मानक मसौदा**

**नेत्र प्रकाशिकी- संपर्क लेंस और संपर्क लेंस देखभाल उत्पाद लेबलिंग**  
(ISO 11978:2017 + AMD 1:2020)

***Draft Indian Standard***

**Ophthalmic optics — Contact lenses and contact lens  
care products Labelling**  
(ISO 11978:2017 + AMD 1:2020)

[ICS 11.040.70]

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Ophthalmic Instruments and Appliances Sectional Committee,  
MHD 05

Last Date for Comments:  
22<sup>nd</sup> May 2024

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**NATIONAL FOREWORD**

*(Adoption clause will be added later)*

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.
- b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards, which are to be substituted in their respective places, are listed below along with their degree of equivalence for the editions indicated:

<i>International Standard</i>	<i>Corresponding Standard</i>	<i>Degree of Equivalence</i>
ISO 15223-1:2012, Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements	IS/ISO 15223-1: 2016 Medical Devices — Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied Part 1 General Requirements (Second Revision )	Identical under single numbering
ISO 18369-1, Ophthalmic optics — Contact lenses — Part 1: Vocabulary, classification system and recommendations for labelling specifications	IS/ISO 18369:2017, Ophthalmic optics Contact lenses Part 1 Vocabulary classification system and recommendations for labeling specifications (First Revision)	Identical under single numbering

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**Note:** The technical content of the document has not been included as it is identical with the corresponding ISO standard. For details, please refer to ISO 11978:2017 or kindly contact:

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**Bureau of Indian Standards**  
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**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.