

SINGAPORE STANDARD

SS 373 : Part 2 : 1994

(ICS 11.040.70)

SPECIFICATION FOR

Optics and optical instruments – Contact lenses

***Part 2 : Soft corneal and scleral contact
lenses***

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SINGAPORE STANDARD
SPECIFICATION FOR
OPTICS AND OPTICAL INSTRUMENTS - CONTACT LENSES -
PART 2 : SOFT CORNEAL AND SCLERAL CONTACT LENSES

FOREWORD

This Singapore Standard was drawn up by the Technical Committee on Specification for Corneal and Scleral Contact Lenses under the direction of the Chemical Standards Committee.

This Singapore is equivalent to ISO/CD 8321-2, 'Optics and optical instruments, Part 2 : Specification for soft corneal and scleral contact lenses'.

Changes in terminology were made to be in-line with the reference standard. In addition, a minimum magnification of 10x is included under Clause 4.4 for defects to be more easily detected. Clause 4.5 is changed to 10x magnification in order to be consistent with the hard lens specification. The tolerances of sagitta specified for water content are changed from ± 0.05 mm to ± 0.03 mm so as to be in-line with the tolerance of the radius and to reduce calculation inaccuracy.

Clause 5.1 has also been amended to include sterility requirement. Three requirements under Clause 6 considered as compulsory labelling, are shifted to Clause 5.2.

Acknowledgement is made for the use of information from the above draft.

NOTE

1. Singapore Standards are subject to periodical review to keep abreast of technological changes and new technical developments. The revisions of Singapore Standards are announced through the issue of either amendment slips or revised editions.
2. Compliance with a Singapore Standard does not exempt users from legal obligations.

1. SCOPE AND FIELD OF APPLICATION

This Singapore Standard specifies requirements for hydrogel contact lenses as supplied by a manufacturer according to a prescription from a practitioner. It applies to hydrogel contact lenses, delivered in the hydrated state.

2. REFERENCES

The following standards contain provisions which, through reference in this text, constitute provisions of this Singapore Standard. At the time of publication the editions indicated were valid. All standards are subject to revision and parties to agreements based on this Singapore Standard are encouraged to investigate the possibility of applying the most recent editions of the standards listed below.

ISO 8320 : 1986	Optics and optical instruments - Contact lenses - Vocabulary and symbols
ISO 8429 : 1986	Optics and optical instruments - Ophthalmology - Graduated dial scale
ISO/DIS 10344	Standardized saline solution for contact lens testing
SS 373 : Part 4 : 1994	Specification for optics and optical instruments - Contact lenses - Determination of diameter of contact lenses

3. DEFINITIONS

For the purpose of this Singapore Standard, the definitions given in ISO 8320 apply.

4. REQUIREMENTS FOR DIMENSIONS AND OPTICAL PROPERTIES

NOTE. It is recognized that the performance of hydrogel lenses depends on fitting methods and varies a great deal with lens design and material.

It is the intention that this standard be viewed as a standard for reproducibility.

4.1 Tolerances. When tested as described in 4.2 and 4.3 the dimensional and optical properties shall be as prescribed, within the appropriate tolerances detailed in Table 1.

4.2 Method Of Test. Each dimension and optical property specified shall be determined using a calibrated measuring instrument with a precision better than one-half of the tolerance specified for the property.

4.3 Test Environment. Lenses shall be tested in standardized saline solution for contact lens testing ISO/DIS 10344 at the ambient temperature specified in the appropriate Singapore standard for the test method used.

NOTE. A manufacturer may specify alternative test conditions (see Clause 6b).

4.4 Inclusions And Surface Imperfections. When examined in SS 373 : Part 7 the lens shall be free of inclusions or surface imperfections that interfere with its intended functional use with a minimum of 10x magnification.

4.5 Edge, Contour And Finish. The lens should appear properly shaped, smooth, polished and within the manufacturers designated tolerances when inspected at 10x magnification.