

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

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भारतीय मानक मसौदा

नेत्र संबंधी उपकरण – अप्रत्यक्ष नेत्रदर्शी

(ISO 10943:2023 MOD)

Draft Indian Standard

Ophthalmic instruments Indirect ophthalmoscopes

(ISO 10943:2023 MOD)

[ICS 11.040.70]

Ophthalmic Instruments and Appliances Sectional Committee,
MHD 05

Last Date for Comments:
23rd May 2024

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 15004-1, Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments	MHD/05/23851 Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments(ISO 15004-1 : 2020, MOD)	Modified
ISO 15004-2, Ophthalmic instruments — Fundamental requirements and test methods — Part 2: Light hazard protection	MHD/05/23852 , Ophthalmic instruments Fundamental requirements and test methods Part 2: Light hazard protection	Identical
IEC 60601-1:2005+A1:2012, Medical electrical equipment — Part 1: General requirements for basic safety and essential performance	MHD/15/22648 Medical Electrical Equipment Part 1 General Requirements for Basic Safety and Essential Performance (IEC 60601-1 : 2020, MOD) (Third Revision)	Modified

In this Standard, reference to IEC 60601-1 has been modified to MHD/15/22648 which is a modified adoption of IEC 60601-1: 2020.

In this Standard, reference to ISO 15004-1 has been modified to MHD/05/23851 which is a modified adoption of ISO 15004-1: 2020.

This standard also makes a reference to the BIS Certification Marking of the product. Details of which is given in National Annex A.

NATIONAL ANNEX A

(National Foreword)

A-1 BIS CERTIFICATION MARKING

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the BIS Act, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

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 10943:2023 or kindly contact:

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Scope:

This document, together with ISO 15004-1 and ISO 15004-2, specifies minimum requirements and test methods for hand-held, spectacle-type, and head-worn indirect ophthalmoscopes for observing indirect images of the eye fundus.

This document takes precedence over ISO 15004-1 and ISO 15004-2, if differences exist.

This document is not applicable to condensing lenses used for indirect ophthalmoscopy or to accessories.

This document is not applicable to table-mounted instruments such as Gullstrand ophthalmoscopes and their derivatives, nor to ophthalmoscopes primarily intended for image capture and/or processing such as those based on scanning laser techniques.