

BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा
दंत चिकित्सा — हाथ के उपकरणों की सामान्य आवश्यकताएँ
भाग 1 नॉन-हिंज्ड हाथ के उपकरण

Draft Indian Standard

Dentistry — General Requirements of Hand Instruments
Part 1 Non-Hinged Hand Instruments

[ICS 11.060.20]

Dentistry Sectional Committee, MHD 08

Last date for comments: **18 July 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:

- Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'
- 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 Indian Standard</i>	<i>Degree of Equivalence</i>
ISO 1942, Dentistry — Vocabulary	IS 17895 : 2023/ISO 1942 : 2020, Dentistry — Vocabulary	Identical
ISO 6507-1, Metallic materials — Vickers hardness test — Part 1: Test method	MTD/03/25819, Metallic Materials — Vickers Hardness Test Part 1: Test Method (<i>Sixth Revision</i>)	Identical

ISO 6508-1:2016, Metallic materials — Rockwell hardness test — Part 1: Test method	IS 1586 (Part 1) : 2018/ISO 6508-1 : 2016, Metallic Materials — Rockwell Hardness Test Part 1 Test Method (<i>Fifth Revision</i>)	Identical
ISO 15223-1, Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	IS 18105 (Part 1) : 2023/ISO 15223-1:2021, Medical Devices — Symbols to be Used with Information to be Supplied by the Manufacturer Part 1 General Requirements (<i>Third Revision</i>)	Identical
ISO 17664-1, Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices	MHD/12/20835, Processing of Health Care Products — Information to be Provided by the Medical Device Manufacturer for the Processing of Medical Devices Part 1 Critical and Semi-Critical Medical Devices	Identical
ISO 17664-2, Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices	MHD/12/20832, Processing of Health Care Products — Information to be provided by the Medical Device Manufacturer for the Processing of Medical Devices Part 2 Non-Critical Medical Devices	Identical
ISO 20417, Medical devices — Information to be supplied by the manufacturer	MHD/14/23491, Medical Devices — Information to be Supplied by the Manufacturer	Identical

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

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test shall be rounded off in accordance with IS 2: 2022 ‘Rules for rounding off numerical values (*second revision*)’.

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 *Bureau of Indian Standards Act, 2016* and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

Scope

This document specifies requirements and test methods common to all non-hinged hand instruments used in dentistry, including materials, hardness, surface finish, resistance to reprocessing and information for marking, although some can have additional specific requirements and test methods.

This document does not specify terms and definitions or classification of specific types of hand instruments.

This document excludes powered instruments. The classification and the shape of working ends of non-hinged hand instruments are excluded from this document.

The technical content of the document has not been enclosed as it is identical with the corresponding ISO standard. For details, please refer to ISO 4865-1:2023 or kindly contact:

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