

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

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भारतीय मानक मसौदा
दंत चिकित्सा - दंत चिकित्सा उपकरणों के लिए सामग्री
भाग 1 स्टेनलेस स्टील

Draft Indian Standard
Dentistry — Materials for Dental Instruments
Part 1 Stainless Steel

ICS 11.060.20

Dentistry Sectional Committee, MHD 08

Last date for comments: 05 April 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 10993-1, Biological evaluation of medical devices — Part 1: Evaluation and testing	IS 17932 (Part 1) : 2023, Biological evaluation of medical devices Part 1: Evaluation and	Modified/Technically Equivalent

within a risk management process testing within a risk management process (ISO 10993-1 : 2018, MOD)

The technical committee has reviewed the provisions of the following International Standards referred in this adopted standard and has decided that they are acceptable for use in conjunction with this standard:

<i>International Standard</i>	<i>Title</i>
ISO 7405	Dentistry — Evaluation of biocompatibility of medical devices used in dentistry
ISO 15510	Stainless steels — Chemical composition

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*)’.

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 *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 stainless steel commonly used in manufacturing dental instruments. It is applicable to stainless steel materials used to manufacture either an entire instrument or a part of the instrument.

It is applicable to single-use and reusable dental instruments, whether it is or it is not connected to a power-driven system.

This document is not applicable to devices and instruments used long-term in the mouth of the patient (e.g. crown, bridges, implants) or to devices and instruments not made of stainless steel. It contains a current selection of stainless steels suitable for use in the manufacture of dental instruments.

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 21850-1: 2020 or kindly contact:

Head
Medical Equipment and Hospital Planning Department
Bureau of Indian Standards
9 Bahadur Shah Zafar Marg
New Delhi-110002
Email: mhd@bis.gov.in
hmhd@bis.gov.in