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BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

दंत चिकित्सा — दंत इम्प्लांट स्थापना और उपचार में उपयोग किए जाने वाले उपकरणों और संबंधित सहायक उपकरणों के लिए सामान्य अपेक्षाएँ

Draft Indian Standard

Dentistry — General Requirements for Instruments and Related Accessories Used in Dental Implant Placement and Treatment

[ICS 11.060.25]

Dentistry Sectional Committee, MHD 08 Last date for comments: **15 June 2025**

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'; and

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:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 1942 Dentistry — Vocabulary	IS 17895 : 2023/ISO 1942 : 2020 Dentistry — Vocabulary	Identical
ISO 2768-1 General tolerances — Part 1: Tolerances for linear and angular dimensions without individual tolerance indications	IS 2102 (Part 1) : 1993/ISO 2768-1 : 1989 General tolerances Part 1 Tolerances for linear and angular dimensions without individual	Identical

	tolerance indications (*third revision*)	
ISO 5832-2 Implants for surgery — Metallic materials — Part 2: Unalloyed titanium	IS/ISO 5832-2 : 2018 Implants for surgery — Metallic materials Part 2 Unalloyed titanium (*first revision*)	Identical
ISO 5832-3 Implants for surgery — Metallic materials — Part 3: Wrought titanium 6-aluminium 4-vanadium alloy	IS 18261 (Part 3) : 2023/ISO 5832-3 : 2021 Implants for surgery — Metallic materials Part 3 Wrought titanium 6-aluminium 4-vanadium alloy (*second revision*)	Identical
ISO 10993-1 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	IS 17932 (Part 1) : 2023 Biological evaluation of medical devices Part 1 Evaluation and testing within a risk management process (ISO 10993-1 : 2018, MOD)	Modified
ISO 11135-1 Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	IS/ISO 11135 : 2014, Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices	Identical
ISO 11137-1 Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	IS/ISO 11137-1 : 2006 Sterilization of health care products — Radiation Part 1 Requirements for development, validation and routine control of a sterilization process for medical devices	Identical
ISO 14155 Clinical investigation of medical devices for human subjects — Good clinical practice	IS/ISO 14155 : 2020 Clinical investigation of medical devices for human subjects — Good clinical practice (*first revision*)	Identical
ISO 14971 Medical devices — Application of risk management to medical devices	IS/ISO 14971 : 2019 Medical devices — Application of risk management to medical devices (*first revision*)	Identical
ISO 15223-1 Medical devices — Symbols to be used with information to be supplied by	IS 18105 (Part 1) : 2023/ISO 15223-1 : 2021 Medical devices — Symbols to be used with	Identical

the manufacturer — Part 1: General requirements	information to be supplied by the manufacturer Part 1 General requirements (*third revision*)	
ISO 17664 Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices	IS 18742 (Part 1) : 2024/ISO 17664-1 : 2021 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 17665-1 Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	IS 18319 : 2024/ISO 17665 : 2024 Sterilization of health care products — Moist heat — Requirements for the development, validation and routine control of a sterilization process for medical devices (*first revision*)	Identical
ISO 7405, Dentistry — Evaluation of biocompatibility of medical devices used in dentistry	IS/ISO 7405 : 2008, Dentistry - Evaluation of biocompatibility of medical devices used in dentistry	Identical

The Committee responsible for the preparation of this standard 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:

International Standard	*Title*
ISO 1043-1	Plastics — Symbols and abbreviated terms — Part 1: Basic polymers and their special characteristics

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*)’. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

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 International Standard specifies general requirements for the manufacture of instruments and related accessories used in the placement of dental implants and further manipulations of connecting parts in the craniofacial area.

It is applicable to single-use and reusable instruments, regardless of whether they are manually driven or connected to a power-driven system.

It is not applicable to the power-driven system itself, nor to the dental implant or to parts intended to be connected to the dental implant.

With regard to safety, this International Standard gives requirements for classification, intended performance, performance attributes, material selection, performance evaluation, manufacture, sterilization and information to be supplied by the manufacturer.

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 13504 : 2012 or kindly contact:

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