Doc No: MHD 08 (25654) WC
June 2024

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

दंत चिकित्सा — दंत रेस्टोरेटिव सामग्री, ल्यूटिंग सामग्री, फिशर सीलेंट और ऑर्थोडॉन्टिक बॉन्डिंग या ल्यूटिंग सामग्री की जीवाणुरोधी गतिविधि का मूल्यांकन

Draft Indian Standard

Dentistry — Evaluation of Antibacterial Activity of Dental Restorative Materials, Luting Materials, Fissure Sealants and Orthodontic Bonding or Luting Materials

[ICS 11.060.10]

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:

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:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 1942, Dentistry — Vocabulary	IS 17895 : 2023/ISO 1942 : 2020, Dentistry — Vocabulary	Identical

ISO 4049, Dentistry — Polymer-based restorative materials	IS 10011 : 2022, Dentistry — Polymer-Based Restorative Materials (ISO 4049 :2019, MOD) (*Second Revision*)	Modified
ISO 6344-3, Coated abrasives — Determination and designation of grain size distribution — Part 3: Microgrit sizes P240 to P5000	PGD/09/23641, Coated Abrasives — Determination and Designation of Grain Size Distribution Part 3 Microgrit Sizes P240 to P5000 (*Second Revision*)	Identical
ISO 9917-1, Dentistry — Water-based cements — Part 1: Powder/liquid acid-base cements	IS/ISO 9917 (Part 1) : 2007, Dentistry — Water-Based Cements Part 1 Powder/Liquid Acid-Base Cements (*First Revision*)	Identical
ISO 9917-2, Dentistry — Water-based cements — Part 2: Resin-modified cements	IS/ISO 9917-2 : 2017, Dentistry — Water-Based Cement Part 2 Resin-Modified Cements (*First 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 10993-5, Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	IS/ISO 10993-5 : 2009, Biological Evaluation of Medical Devices Part 5 Tests for in vitro Cytotoxicity	Identical
ISO 10993-12, Biological evaluation of medical devices — Part 12: Sample preparation and reference materials	IS/ISO 10993-12 : 2021, Biological Evaluation of Medical Devices Part 12 Sample Preparation and Reference Materials	Identical
ISO 10993-18, Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process	IS/ISO 10993-18 : 2020, Biological Evaluation of Medical Devices Part 18 Chemical Characterization of Medical Device Materials within a Risk Management Process	Identical

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:

International Standard *Title*

ISO 7405	Dentistry — Evaluation of biocompatibility of medical devices used in dentistry

In reporting the result of a test or analysis made in accordance with this standard, is to be rounded off, it shall be done in accordance with IS 2 : 2022 ‘Rules for rounding off numerical values (*second revision*)’.

Scope

This document specifies test methods for the evaluation of dental restorative materials, luting materials, fissure sealants and orthodontic bonding or luting materials that are claimed by their respective manufacturers to exert “antibacterial” effects.

NOTE Materials for pulp capping (e.g. calcium hydroxide formulations), endodontic filling materials, dental implants or implant systems, nightguards and additive manufactured (e.g. 3D-printed) materials are not covered in this document.

This document does not cover tests on the effectiveness of sterilization or disinfection procedures. This document cannot be used to demonstrate a lack of microbial contamination of medical devices used in dentistry.

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 3990:2023 or kindly contact:

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