

**BUREAU OF INDIAN STANDARDS**

**DRAFT FOR COMMENTS ONLY**

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*भारतीय मानक मसौदा*

**दंत चिकित्सा — पूर्व कैप्सूलयुक्त दंत अमलगम**

*Draft Indian Standard*

**Dentistry — Pre-capsulated Dental Amalgam**

**[ICS 11.060.10]**

Dentistry Sectional Committee, MHD 08

Last date for comments: **30 May 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:

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
ISO 286-2 Geometrical product specifications (GPS) — ISO code system for tolerances on linear sizes — Part 2: Tables of standard tolerance classes and limit deviations for holes and shafts	IS 919 (Part 2) : 2014/ISO 286-2 : 2010 Geometrical product specifications (GPS) — ISO code system for tolerances on linear sizes Part 2 Tables of standard tolerance classes and limit deviation for holes and shafts ( <i>second revision</i> )	Identical
ISO 1942 Dentistry — Vocabulary	IS 17895 : 2023/ISO 1942 : 2020 Dentistry — Vocabulary	Identical

ISO 3310-1 Test sieves — Technical requirements and testing — Part 1: Test sieves of metal wire cloth	IS 460 (Part 1) : 2020 Test sieves — Specification Part 1 Wire cloth test sieves ( <i>fourth revision</i> )	Technically Equivalent
ISO 3864-2 Graphical symbols — Safety colours and safety signs — Part 2: Design principles for product safety labels	IS 16449 (Part 2) : 2021/ISO 3864-2 : 2016 Graphical symbols — Safety colours and safety signs Part 2 Design principles for product safety labels ( <i>first revision</i> )	Identical
ISO 6344-3 Coated abrasives — Determination and designation of grain size distribution — Part 3: Microgrit sizes P240 to P5000	IS 15287 (Part 3) : 2024/ISO 6344-3 : 2021 Coated abrasives — Determination and designation of grain size distribution Part 3 microgrit sizes P240 to P5000 ( <i>second revision</i> )	Identical
ISO 21920-2 Geometrical product specifications (GPS) — Surface texture: Profile — Part 2: Terms, definitions and surface texture parameters	IS 18432 (Part 2) : 2023/ISO 21920-2 : 2021 Geometrical product specifications (GPS) — Surface texture — Profile Part 2 Terms, definitions and surface texture parameters	Identical
ISO 15223-1:2021, 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 23325:2020 Dentistry — Corrosion resistance of dental amalgam	IS 18494 : 2024/ISO 23325 : 2020 Dentistry — Corrosion resistance of dental amalgam	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 7488	Dentistry — Mixing machines for dental amalgam
	Globally Harmonized System of Classification and Labelling of Chemicals (GHS). United Nations, New York and Geneva, 9th Revised Edition, 2021, eISBN 978-92-1-005213-9
	Recommendations on the Transport of Dangerous Goods, Model Regulations. United Nations, New York and Geneva, 22st Edition (Vol.1), 2022, eISBN 978-92-1-005219-1

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 document specifies the requirements and test methods for dental amalgam products supplied to the user in capsules, pre-dosed with dental amalgam alloy powder and dental mercury in quantities suitable for the creation of a single dental restoration.

This document specifies the requirements and test methods for the capsule and the requirements for packaging and marking.

This document is not applicable to other metallic materials in which an alloy powder reacts with an alloy that is liquid at ambient temperature to produce a solid metallic material intended for dental restoration.

This document is restricted to dental amalgam products marketed in pre-capsulated form, alone. Other products intended for use in the production of dental amalgam restorations (dental amalgam alloy as a free-flowing powder supplied in bulk masses, dental amalgam alloy powder supplied as compressed tablets and dental mercury sachets) are described in ISO 24234.

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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 20749 : 2023 or kindly contact:

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