

BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा
दंत चिकित्सा — बाहरी दाँत ब्लिचिंग उत्पाद

Draft Indian Standard
Dentistry — External Tooth Bleaching Products

[ICS 97.170]

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 1042, Laboratory glassware — One-mark volumetric flasks	IS 915 : 2012/ISO 1042 : 1998, Laboratory Glassware — One-Mark Volumetric Flasks (<i>Third Revision</i>)	Identical
ISO 1942, Dentistry — Vocabulary	IS 17895 : 2023/ISO 1942 : 2020, Dentistry — Vocabulary	Identical
ISO 3696, Water for analytical laboratory use — Specification and test methods	IS 1070 : 2023, Reagent grade water - Specification (<i>Fourth Revision</i>)	Not Equivalent

ISO 6344-2, Coated abrasives — Determination and designation of grain size distribution — Part 2: Macrogrit sizes P12 to P220	PGD/09/23647, Coated Abrasives — Determination and Designation of Grain Size Distribution Part 2 Macrogrit Sizes P12 to P220 (<i>First Revision</i>)	Identical
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 (<i>Second Revision</i>)	Identical
ISO 8601-1, Date and time — Representations for information interchange — Part 1: Basic rules	IS/ISO 8601-1 : 2019, Date and Time - Representations For Information Interchange Part 1 Basic Rules	Identical
ISO 8601-2, Date and time — Representations for information interchange — Part 2: Extensions	IS/ISO 8601-2 : 2019, Date and Time — Representations for Information Interchange Part 2 Extensions	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:

<i>International Standard</i>	<i>Title</i>
ISO/CIE 11664-1	Colorimetry — Part 1: CIE standard colorimetric observers
ISO/CIE 11664-2	Colorimetry — Part 2: CIE standard illuminants
ANSI/ADA Spec. No. 41	Recommended Standard Practices for Biological Evaluation Of Dental Materials

This Standard includes modification of cross reference from ISO 6344-1 to two parts i.e. ISO 6344-2 and ISO 6344-3.

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 the requirements and test methods for external tooth bleaching products. These products are intended for use in the oral cavity, either by professional application (in-office tooth bleaching products) or consumer application (professional or non-professional home use of tooth bleaching products), or both. It also specifies requirements for their packaging, labelling and manufacturer's instructions for use.

This document is not applicable to tooth bleaching products:

- specified in ISO 11609;
- intended to change colour perception of natural teeth by mechanical methods (e.g. stain removal) or using restorative approaches, such as veneers or crowns;
- auxiliary or supplementary materials (e.g. tray materials) and instruments or devices (e.g. lights) that are used in conjunction with the bleaching products.

This document does not specify biological safety aspects of tooth bleaching products.

NOTE Maximum concentration of a bleaching agent for professional or non-professional use is subject to each country's regulatory body.

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 28399:2021 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