#### **BUREAU OF INDIAN STANDARDS**

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## भारतीय मानक मसौदा दंत चिकित्सा - एंडोडॉन्टिक अवशोषक बिंदु

# Draft Indian Standard Dentistry — Endodontic Absorbent Points

#### ICS 11.060.10

Dentistry Sectional Committee, MHD 08 Last date for comments: 13 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:

- 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 3630-1, Dentistry — Endodontic instruments — Part 1: General requirements	IS 17859 (Part 1) : 2022/ISO 3630- 1:2019, Dentistry Endodontic instruments Part 1: General requirements	Identical
coding system for rotary	IS/ISO 6360-1 : 2004/ISO 6360- 1:2004, Dentistry - Number coding system for rotary instruments - Part 1: General characteristics	Identical

Representations for information	IS/ISO 8601-1 : 2019, Date and Time Representations For Information Interchange Part 1: Basic Rules	Identical
Symbols to be used with information to be supplied by the	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	Identical
,	MHD/14/23491, Medical devices Information to be supplied by the manufacturer	Identical

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 the requirements and test methods for sterilized absorbent points used in endodontic procedures. Absorbent points are marketed sterilized or non-sterilized. The requirements apply to absorbent points which have been sterilized once in a manner approved by the manufacturer. This document specifies numerical systems and a colour-coding system for designating the sizes of absorbent points.

Clause 7 specifies the labelling and packaging needed, including the instructions for use. A claim by the manufacturer that the contents of the unopened pack are sterile is the responsibility of the manufacturer (see Table 2). This document does not specify requirements or test methods for sterility.

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 7551:2023 or kindly contact:

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