

BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा

दंत चिकित्सा — पाउडर जेट हैंडपीस और पाउडर्स

Draft Indian Standard

Dentistry — Powder Jet Handpieces and Powders

[ICS 11.060.20]

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 1942, Dentistry — Vocabulary	IS 17895 : 2023/ISO 1942 : 2020, Dentistry — Vocabulary	Identical
ISO 5349-1, Mechanical vibration — Measurement and evaluation of human exposure to hand-transmitted vibration — Part 1: General requirements	IS/ISO 5349-1:2001, Mechanical vibration — Measurement and evaluation of human exposure to hand-transmitted vibration Part 1 General requirements (<i>First Revision</i>)	Identical

ISO 5349-2, Mechanical vibration — Measurement and evaluation of human exposure to hand-transmitted vibration — Part 2: Practical guidance for measurement at the workplace	IS/ISO 5349-2:2001, Mechanical vibration — Measurement and evaluation of human exposure to hand-transmitted vibration Part 2 Practical guidance for measurement at the workplace (<i>First Revision</i>)	Identical
ISO 7494-1, Dentistry — Stationary dental units and dental patient chairs — Part 1: General requirements	IS 6116 (Part 1) : 2021/ISO 7494-1:2018, Dentistry — Stationary Dental Units and Dental Patient Chairs Part 1 General Requirements (<i>Second Revision</i>)	Identical
ISO 9168, Dentistry — Hose connectors for air driven dental handpieces	IS 12764 : 2019/ISO 9168 : 2009, Dentistry — Hose Connectors for Air Driven Dental Handpieces (<i>Second Revision</i>)	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 14971, Medical devices — Application of risk management to medical devices	IS/ISO 14971 : 2019, Medical Devices — Application of Risk Management to Medical Devices (<i>First Revision</i>)	Identical
ISO 15223-1, 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 17664-1, 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	MHD/12/20835, 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
IEC 60601-1, Medical electrical equipment — Part 1: General requirements for basic safety and essential performance	IS 13450 (Part 1) : 2024, Medical Electrical Equipment Part 1 General Requirements for Basic Safety and Essential Performance (IEC 60601-1 : 2020, MOD) (<i>Third Revision</i>)	Modified

IEC 61672-1, Electroacoustics - Sound level meters - Part 1: Specifications	IS 15575 (Part 1) : 2016/IEC 61672-1 : 2013, Electroacoustics— Sound Level Meters Part 1 Specifications (<i>First Revision</i>)	Identical
IEC 62366-1, Medical devices — Part 1: Application of usability engineering to medical devices	IS 17922 (Part 1) : 2023/IEC 62366-1 : 2015 + AMD 1 : 2020, Medical Devices Part 1 Application of Usability Engineering (<i>First Revision</i>)	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 9687	Dentistry — Graphical symbols for dental equipment
ISO 11014	Safety data sheet for chemical products — Content and order of sections
ISO 21531	Dentistry — Graphical symbols for dental instruments
IEC 80601-2-60	Medical electrical equipment — Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment

This standard includes modification of cross reference from ISO 17664 to ISO 17664-1. Wherever reference to ISO 17664 occurs in the text, ISO 17664-1 has to be substituted.

This standard also includes modification of cross reference from IEC 60601-1:2005 + (AMD1:2012) to IEC 60601-1. Wherever reference to IEC 60601-1:2005 + (AMD1:2012) occurs in the text, IEC 60601-1 has to be substituted.

This standard also includes modification of cross reference from IEC 80601-2-60:2012 to IEC 80601-2-60. Wherever reference to IEC 80601-2-60:2012 occurs in the text, IEC 80601-2-60 has to be substituted.

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 general requirements, test methods, manufacturer's information, marking and packaging, independently of the design of the powder jet handpieces (see Figure 1).

This document applies to powder jet handpieces and their associated powders for use in the field of dentistry. They are used on patients to remove dental debris, discolourations and plaque and to clean and polish teeth where abrasion is a side effect.

It is also applicable to powder jet handpieces and their associated powders that are used in dentistry for air driven abrasion, e.g. minimally invasive cavity preparation, preparation of surfaces for adhesives and for the removal of cement residues where abrasion is part of the desired outcome.

This document is not applicable for the dental units that are employed to supply the powder jet handpieces.

This document is not applicable to dental prophylaxis handpieces (contra angles), or electrically driven plaque removers (scalers) or multifunctional handpieces (syringes).

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 20608:2018 or kindly contact:

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