

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

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भारतीय मानक मसौदा
**दंत चिकित्सा — अस्थायी स्वास्थ्य देखभाल वातावरण में उपयोग के
लिए पोर्टेबल दंत उपकरण
भाग 1 सामान्य अपेक्षाएँ**

Draft Indian Standard
**Dentistry — Portable Dental Equipment for use in Non-
Permanent Healthcare Environment
Part 1 General Requirements**

[ICS 11.060.20]

Dentistry Sectional Committee, MHD 08

Last date for comments: **15 June 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 1942	Dentistry	—	Vocabulary	IS 17895 : 2023/ISO 1942 : 2020 Dentistry — Vocabulary	Identical
ISO 4180 : 2019	Packaging — Complete, filled transport packages — General rules for	—		IS 9733 : 2024/ISO 4180 : 2019 Packaging — Complete, filled transport packages — General rules for the compilation of	Identical

the compilation of performance test schedules
performance test schedules (*second revision*)

IEC 60529 : 1989/Amd 1 : 1999 Degrees of protection provided by enclosures (IP Code)	IS/IEC 60529 : 2001 Degrees of protection provided by enclosures (IP Code)	Identical
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IEC 60601-1 : 2005/Amd 1 : 2012 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
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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
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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:

<i>International Standard</i>	<i>Title</i>
ISO 21530	Dentistry — Materials used for dental equipment surfaces — Determination of resistance to chemical disinfectants
IEC 80601-2-60	Medical electrical equipment — Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment

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 general requirements and test methods for portable dental equipment for use in non-permanent healthcare environments.

Portable dental equipment within the scope of this document includes portable dental units, portable patient chairs, portable operator's stools, portable operating lights, portable suction source equipment, portable air compressors and other portable dental equipment in instances where these devices are designed and constructed to be transported for use in non-permanent healthcare environments.

NOTE Particular requirements for specific types of portable dental equipment for use in non-permanent healthcare environments are specified in subsequent parts of this document.

This document does not apply to stationary dental equipment, wearable equipment (such as headlamps and loupes), mobile dental equipment or portable dental equipment that is not intended to be used in non-permanent healthcare environments or not designed to be disassembled, folded or packed for human transport between non-permanent healthcare environments. Also, requirements for stationary dental equipment that can be installed in a dental mobile medical facility (e.g. vehicular or containerized mobile dental clinic) are not considered in this document.

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 23402-1 : 2020 or kindly contact:

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