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BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

दंत चिकित्सा - इंट्रोरल कैमरा

Draft Indian Standard

Dentistry — Intraoral Camera

ICS 11.060.20

Dentistry Sectional Committee, MHD 08 Last date for comments: 05 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 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	Modified/Technically Equivalent

	process (ISO 10993-1 : 2018, MOD)	
ISO 15223-1, Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — 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 (*Third Revision*)	Identical
ISO 17664-1, Processing of health care products — Information to be provided by the medical device manufacturer for the processing of 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	MHD/15/22648, Medical electrical equipment : Part 1 General requirements for basic safety and essential performance (*Third Revision*)	Modified/Technically Equivalent
IEC 60601-1-6, Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	MHD/15/22653, Medical electrical equipment : Part 1 General requirements for basic safety and essential performance, Section 6 Usability (*First revision*)	Modified/Technically Equivalent
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	Identical
IEC 62471, Photobiological safety of lamps and lamp systems	IS 16108 : 2012/IEC 62471:2006, Photobiological safety of lamps and lamp systems	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:

International Standard	*Title*
ISO 9687	Dentistry — Graphical symbols for dental equipment

IEC 80601-2-60	Medical electrical equipment — Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment

This standard alters the reference from ISO 17664 to ISO 17664-1, wherever ISO 17664 appears in this standard it shall be read as ISO 17664-1.

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 requirements and test methods for intraoral cameras used in dentistry on patients for pictorial representation of oral cavities in order to support diagnosis and facilitate patient information. It specifies requirements, test methods, instructions for use and marking.

This document is not applicable to:

a) powered polymerization activators for polymerization of dental materials;
b) exclusively extraoral camera equipment to prepare overviews or to record treatments;
c) dental microscopes for minimally invasive treatments;
d) medical endoscopes;
e) camera handpieces for tooth illumination (transillumination);
f) CAD or CAM scanner handpieces;
g) combinations of dental instruments with camera functions;
h) cameras for endodontic purposes;
i) devices for root canal inspection (endoscopic microcameras);
j) cameras for tool navigation;
k) cameras for determination of tooth colour.

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 23450: 2021 or kindly contact:

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