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BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

चिकित्सा विद्युत उपकरण

भाग 2 बुनियादी सुरक्षा और आवश्यक प्रदर्शन के लिए विशेष आवश्यकताएँ

अनुभाग 75 फोटोडायनामिक थेरेपी और फोटोडायनामिक निदान उपकरण की बुनियादी सुरक्षा और आवश्यक प्रदर्शन के लिए विशेष आवश्यकताएं

(IEC 60601-2-75: 2023, संशोधित)

Draft Indian Standard

Medical electrical equipment

Part 2 Particular requirements for the basic safety and essential performance

Section 75 Photodynamic therapy and photodynamic diagnosis equipment

(IEC 60601-2-75: 2023, MOD)

[ICS 11.040.01]

Electromedical, Diagnostic Imaging and Radiotherapy Equipment Sectional Committee, MHD 15	Last date for comments: 17 May, 2024

NATIONAL FOREWORD

(*Adoption clause will be added later*)

The text of IEC 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 Standard also exists. 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*
IEC 60601-1: 2005, Medical electrical equipment — Part 1: General requirements for basic safety and essential performance + AMD 1: 2012 + AMD 2: 2020	IS 13450 (Part 1): 2024 Medical electrical equipment Part 1 General requirements for basic safety and essential performance (IEC 60601-1: 2020, MOD) (*third revision*)	Modified
IEC 60601-2-22:2019, Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment	IS 13450 (Part 2/Sec 22): 2021 Medical electrical equipment Part 2 Particular requirements for basic safety and essential performance Section 22 surgical cosmetic therapeutic and diagnostic laser equipment *(first revision)*	Identical
IEC 62471:2006, Photobiological safety of lamps and lamp systems	IS 16108: 2012 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 these are acceptable for use in conjunction with this standard:

International Standard	*Title*
IEC 60601-2-57:2011	Medical electrical equipment – Part 2-57: Particular requirements for basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
IEC 60825-1:2014	Safety of laser products – Part 1: Equipment classification and requirements

This standard is a modified adoption as the cross-referred Indian standard, IS 13450 (Part 1): 2024 is a modified adoption of IEC 60601-1: 2020. IEC 60601-1: 2020 is the consolidated version of IEC 60601-1: 2005 + AMD1: 2012 + AMD2: 2020 (Edition 3.2).

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 or analysis 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.

The standard also makes a reference to the BIS Certification Marking of the product, details of which are given in National Annex A.

Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of PHOTODYNAMIC THERAPY AND PHOTODYNAMIC DIAGNOSIS EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant. HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this document are not covered by specific requirements in this document except in 7.2.13 and 8.4.1 of the general standard.

This document applies to PHOTODYNAMIC THERAPY AND PHOTODYNAMIC DIAGNOSIS EQUIPMENT used for compensation or alleviation of disease, injury or disability.

In the case of combined equipment (e.g. equipment additionally provided with a function or an APPLIED PART for the target area) such equipment shall also comply with any particular standard specifying safety requirements for the additional function.

This particular standard does not apply to:

- Light therapy equipment intended for use in photothermal ablation, coagulation, and hyperthermia;
- Low-level laser therapy equipment not intended for use with a PHOTOSENSITIZER;
- Illumination equipment intended for use in observation, monitoring, and diagnosis, not intended for use with a PHOTOSENSITIZER.

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.

The technical content of the document has not been enclosed as it is identical with the corresponding IEC standard. For details, please refer to IEC 60601-2-75: 2023 or kindly contact:

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