

BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा

चिकित्सीय विद्युत् उपस्कर

**भाग 2 बुनियादी सुरक्षा और आवश्यक प्रदर्शन के लिए विशेष आवश्यकताएं
अनुभाग 41 निदान के लिए शल्य चिकित्सा के प्रकाश उपकरण और प्रकाश उपकरण**

(IEC 60601-2-41: 2021, संशोधित)

(पहला पुनरीक्षण)

Draft Indian Standard

Medical Electrical Equipment

**Part 2 Particular Requirements for Basic Safety and Essential
Performance**

Section 41 Surgical luminaires and luminaires for diagnosis

(IEC 60601-2-41: 2021, MOD)

(First Revision)

[ICS 11.040.20; 11.040.55; 11.040.99]

Electromedical, Diagnostic Imaging and Radiotherapy
Equipment Sectional Committee, MHD 15

Last date for comments:
23 February, 2024

NATIONAL FOREWORD

(Adoption clause will be added later)

This standard was originally published as IS 13450 (Part 2/Sec 41): 2020 which was an identical adoption of IEC 60601-2-41: 2009 Medical electrical equipment – Part 2-41 Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. The first revision has been taken up to align the Indian Standard with the current version of IEC 60601-2-41: 2021.

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:

- Wherever the words ‘International Standard’ appear referring to this standard, they should be read as ‘Indian Standard’; and
- 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:

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
IEC 60601-1: 2005, Medical electrical equipment — Part 1: General requirements for basic safety and essential performance + AMD 1: 2012	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 62471: 2006, Photobiological safety of lamps and lamp systems	IS 16108: 2012 / IEC 62471: 2006 Photobiological safety of lamps and lamp systems	Identical
IEC 60529: 1989, Degrees of protection provided by enclosures (IP Code) + AMD1: 1999 + AMD2: 2013	IS/IEC 60529: 2001 Degrees of protection provided by enclosures (IP Code)	Identical
IEC 60601-1-2: 2014, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests	IS 13450 (Part 1/Sec 2): 2024 Medical Electrical Equipment Part 1 General Requirements for Basic Safety and Essential Performance Section 2 Electromagnetic Disturbances — Requirements and Tests (IEC 60601-1-2: 2020, MOD) (<i>second revision</i>)	Modified
IEC 60601-1-6:2014, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability	IS 13450 (Part 1/Sec 6): 2020/ IEC 60601-1-6: 2010 Medical Electrical Equipment Part 1 General Requirements for Basic Safety and Essential Performance Section 6 Collateral standard: Usability	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:

<i>International Standard</i>	<i>Title</i>
ISO/CIE 11664-1	Colorimetry – Part 1: CIE standard colorimetric observers
ISO/CIE 19476:2014	Characterization of the performance of illuminance meters and luminance meters

ANSI C78.377:2017	Specifications for the Chromaticity of SolidState Lighting (SSL) Products
CIE 13.3:1995	Method of Measuring and Specifying Colour Rendering properties of Light Sources
CIE 15:2018	Colorimetry

This standard is a modified adoption as the corresponding Indian standards (Column 2) in the first table above are not identical to the referred International Standards (Column 1) as given below:

- a. IS 13450 (Part 1/Sec 2): 2024 is a modified adoption of IEC 60601-1-2: 2020 which is a consolidated version of IEC 60601-1-2: 2014 + AMD1: 2020 (Edition 4.1).
- b. 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).

The standard also makes a reference to the BIS Certification Marking of the product, details of which are 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 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.

Introduction

This particular standard concerns the basic safety and essential performance of SURGICAL LUMINAIRES and LUMINAIRES FOR DIAGNOSIS.

It amends and supplements IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, hereinafter referred to as the "general standard".

The requirements of this particular standard take priority over those of the general standard.

Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE OF SURGICAL LUMINAIRES and LUMINAIRES FOR DIAGNOSIS, hereafter referred to as ME EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME EQUIPMENT 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 EQUIPMENT, as relevant.

This particular standard does not apply to

- headlights;
- endoscopes, laparoscopes and their light sources, which are covered by IEC 60601-2-18;
- luminaires used in dentistry, which are covered by ISO 9680;
- luminaires for general purposes, which are covered by IEC 60598-2-1 and IEC 60598-2-4;
- luminaires dedicated to therapeutic purposes;
- special purpose lights with different conditions of use such as light sources intended solely for decontamination of air and surfaces, UV lights for dermatological diagnosis, slit lamps for ophthalmology, lights for surgical microscopes and lights for surgical navigation systems;
- lights connected to surgical instruments, such as luminous retractors;
- luminaires for emergency lighting, which are covered by IEC 60598-2-22.

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 modified adoption of IEC standard. For details, please refer to IEC 60601-2-41: 2021 or kindly contact:

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