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Medical electrical equipment –

Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis

Appareils électromédicaux –

*Partie 2-41:
Règles particulières de sécurité pour les éclairages
chirurgicaux et les éclairages de diagnostic*

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis

FOREWORD

- 1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International Standard IEC 60601-2-41 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this standard is based on the following documents:

FDIS	Report on voting
62D/344/FDIS	62D/352/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 3.

Annex AA is for information only.

In this Particular Standard the following print types are used:

- requirements, compliance with which can be tested, and definitions: in roman type;
- notes, explanations, advice, introductions, general statements, exceptions and references: in smaller type;
- *test specifications: in italic type;*
- TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD IEC 60601-1 OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

The committee has decided that this publication remains valid until 2005.

At this date, in accordance with the committee's decision, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

A bilingual version of this standard may be issued at a later date.

INTRODUCTION

This Particular Standard concerns the safety of SURGICAL LUMINAIRES and LUMINAIRES FOR DIAGNOSIS. It amends and supplements IEC 60601-1 (second edition 1988), hereinafter referred to as the General Standard. The requirements of this Particular Standard take priority over those of the General Standard, entitled "*Medical electrical equipment – Part 1: General requirements for safety.*"

A "Guidance and rationale" for the requirements of this Particular Standard is included in annex AA.

It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this Standard.

An asterisk (*) inserted before a clause or subclause number indicates that some explanatory notes are given in annex AA at the end of this Particular Standard.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows.

1 Scope and object

This clause of the General Standard applies except as follows:

*1.1 Scope

Addition:

This Particular Standard details the requirements to be applied to SURGICAL LUMINAIRES and LUMINAIRES FOR DIAGNOSIS as defined in 2.101 to 2.105, hereinafter referred to as EQUIPMENT.

This 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 of an emergency lighting, which are covered by IEC 60598-2-22.

NOTE Luminaires used in clinical areas of hospitals other than those defined in 2.101 to 2.105 are covered by IEC 60598-2-25.