

تقديم

الهيئة العامة للغذاء والدواء جهة مستقلة الغرض الأساسي لها هو القيام بتنظيم ومراقبة الغذاء والدواء والأجهزة والمنتجات الطبية والتشخيصية، ومن مهامها وضع اللوائح الفنية والمواصفات في مجالات الغذاء والدواء والأجهزة والمنتجات الطبية سواء كانت مستوردة أو مصنعة محلياً بواسطة لجان فنية متخصصة، وقد قام قطاع الأجهزة والمنتجات الطبية بالهيئة ضمن برنامج عمل الفريق رقم (62 SFDA/MDS/TC) "فريق عمل مواصفات الأجهزة الكهربائية في التطبيقات الطبية" بتبني المواصفة الدولية رقم (IEC 60601-2-22:2012) "الأجهزة الكهربائية الطبية-الجزء 2-22: المتطلبات الخاصة للسلامة والأداء الأساسيين لأجهزة الليزر التشخيصية والعلاجية والتجميلية والجراحية"، والتي أصدرتها "المنظمة الدولية الكهروتقنية" وذلك بلغتها الأصلية. وقد اعتمدت هذه المواصفة كمواصفة سعودية متبناة بالتعديل بلغتها الأصلية وذلك في اجتماع مجلس الإدارة رقم () والذي عقد بتاريخ (14.././.. هـ) الموافق (20.././.. م).

- التعديلات مشار إليها في ملحق التعديلات.

Foreword

Saudi Food and Drug Authority (SFDA) is an independent organization with main purpose of regulating and monitoring of foods, drugs and medical devices. One of SFDA functions is to issue national Standards /Technical Regulation in the fields of foods, drugs and medical devices, whether imported or manufactured locally, through specialized technical committees (TCs).SFDA medical devices sector through the work program of technical committee (SFDA/MDS/TC62) "Electrical equipment in medical practice" has adopted the International Standard No. (IEC 60601-2-22:2012) "Medical electrical equipment-Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment" issued by "International electrotechnical Commission" in its original language. This standard is adopted with modifications in its original language and has been approved as national standard by SFDA board of directors in its meeting No () Held on (.././14..AH), agreed with (.././20.. G).

- The modifications are mentioned in the Modifications Annex.

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of laser equipment for either surgical, therapeutic, medical diagnostic, cosmetic, or veterinary applications, intended for its use on humans or animals, classified as a CLASS 3B or CLASS 4 LASER PRODUCT as defined by 3.22 and 3.23 in IEC 60825-1, hereafter referred to as LASER EQUIPMENT.

Throughout this International Standard, light emitting diodes (LED) are included whenever the word “laser” is used.

NOTE 1 Refer to Definition 3.49 in IEC 60825-1.

NOTE 2 Laser products for these applications classified as a CLASS 1, 1M, 2, 2M or CLASS 3R LASER PRODUCT, are covered by IEC 60825-1 and IEC 60601-1.

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 standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the General Standard.

NOTE See also 4.2 of the General Standard.

This standard can also be applied to surgical, cosmetic, therapeutic and diagnostic laser equipment used for compensation or alleviation of disease, injury or disability.

Modifications Annex

Project: SFDA.MD.62.DS.IEC 60601-2-22:2012

#	رقم الصفحة Page No.	رقم البند/البند الفرعي Clause/Subclause No.	فقرة/ صورة/ جدول Paragraph/ Figure/ Table/	نوع الملاحظة* Comment type	الملاحظات Comments	التعديل المقترح Modification
1		201.7.2.101		te	ADDITIONAL ITEMS	Add item: c) If Storage temperature between -5°C to +55°C, it shall be indicated on the label.
2		201.7.9		te	ACCOMPANYING DOCUMENTS	Add item: Accompanying documents shall be written in Arabic if used by lay person
3		201.8.11.101		te	Title "Use of water for cooling"	the words "water" changed to "liquid"

Comment type: ge = general te = technical ed = editorial