

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 سواءً كانت مستوردة أو مصنعة محلياً بواسطة لجان فنية متخصصة، وقد قام قطاع الأجهزة والمنتجات الطبية بالهيئة ضمن برنامج عمل الفريق رقم (SFDA/MDS/TC 62) "فريق عمل مواصفات الأجهزة الكهربائية في التطبيقات الطبية" بتبني المواصفة الدولية رقم (IEC 60601-2-4:2010/AMD1:2018) "الأجهزة الكهربائية الطبية - الجزء 2-4: المتطلبات الخاصة بسلامة أجهزة الصدمات الكهربائية للقلب"، والتي أصدرتها "المنظمة الدولية الكهروتقنية" وذلك بلغتها الأصلية. وقد اعتمدت هذه المواصفة كمواصفة سعودية متبناة بالمطابقة بلغتها الأصلية وذلك في اجتماع مجلس الإدارة رقم () والذي عقد بتاريخ (14.././.. هـ) الموافق (20.././.. م).

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 60601-2-4:2010/AMD1:2018) "Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators" issued by "International electrotechnical Commission" in its original language. This standard is identically adopted 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).

201.1 Scope, object and related standards

Clause 1 of the general standard¹ applies, except as follows:

201.1.1 * Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of CARDIAC DEFIBRILLATORS, hereafter referred to as ME 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 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 particular standard does not apply to implantable DEFIBRILLATORS, remote control DEFIBRILLATORS, or separate stand-alone cardiac monitors (which are standardized by IEC 60601-2-27:2011 **Error! Reference source not found.**²). Cardiac monitors which use separate ECG monitoring electrodes are not within the scope of this standard unless they are used as the sole basis for AED rhythm recognition detection or beat detection for synchronized cardioversion. DEFIBRILLATOR electrodes as described in 201.108 can also be used for ECG monitoring; however, due to the larger electrode area, the requirements of IEC 60601-2-27 are not applicable for DEFIBRILLATOR ELECTRODES.

Defibrillation waveform technology is evolving rapidly. Published studies indicate that the effectiveness of waveforms varies. The choice of a particular waveform including waveshape, delivered energy, efficacy, and safety has been specifically excluded from the scope of this standard.

However, due to the critical importance of the therapeutic waveform, comments have been added to the rationale which addresses considerations in waveform selection.

¹ The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

² Numbers in square brackets refer to the bibliography.