تقديم

الهيئة جهة مستقلة الغرض الأساسي لها هو القيام بتنظيم ومراقبة الغذاء والدواء والأجهزة والمنتجات الطبية، ومن مهامها وضع اللوائح الفنية والمواصفات في مجالات الغذاء والدواء والأجهزة والمنتجات الطبية سواءً كانت مستوردة أو مصنعة محلياً، 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 المواصـــــــفة الدولية رقم (IEC 80601-2-49: 2018) " الأجهزة الكهربائية الطبية-الجزء 2-49: المتطلبات الخاصة للسلامة والأداء الأساسيين لأجهزة مراقبة المريض متعددة الوظائف "، والتي أصدرتها "المنظمة الدولية الكهروتقنية" وذلك بلغتها الأصلية. وقد اعتمدت هذه المواصفة كمواصفة سعودية متبناة بالمطابقة بلغتها الأصلية وقد تم إقرار تبني المواصفة من معالي الرئيس التنفيذي للهيئة بقرار رقم (.....) وتاريخ .....

Foreword

The Saudi Food and Drug Authority (SFDA) is an independent organization mainly responsible for regulating imported/local food, drug and medical devices which includes, inter alia, setting their standards. International Standard No. (IEC 80601-2-49: 2018) “ Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors” issued by “International electrotechnical Commission” has been adopted identically in its original language. This standard is adopted with modifications in its original language as a national standard and approved by SFDA CEO decision No (…) on (date)

Scope:

Replacement:

This part of the 80601 International Standard applies to BASIC SAFETY and ESSENTIAL PERFORMANCE requirements of MULTIFUNCTION PATIENT MONITORS as defined in 201.3.201, hereafter referred to as ME EQUIPMENT or MEDICAL ELECTRICAL SYSTEMS. This particular standard applies to MULTIFUNCTION PATIENT MONITORS intended for use in professional healthcare facilities as well as in the EMERGENCY MEDICAL SERVICE ENVIRONMENT or the HOME HEALTHCARE ENVIRONMENT.

The scope of this document is restricted to ME EQUIPMENT or MEDICAL ELECTRICAL SYSTEMS intended for connection to a single PATIENT that has two or more PHYSIOLOGICAL MONITORING UNITS.

NOTE For purposes of this document, a pregnant mother and her fetus(es) are considered a single PATIENT.

This document does not specify requirements for individual PHYSIOLOGICAL MONITORING UNITS such as ECG, invasive pressure and pulse oximetry. The particular standards related to these PHYSIOLOGICAL MONITORING UNITS specify requirements from the perspective of stand-alone ME EQUIPMENT. This particular standard addresses the additional requirements related to MULTIFUNCTION PATIENT MONITORS.MULTIFUNCTION PATIENT MONITORS can be integrated into other ME EQUIPMENT or MEDICAL ELECTRICAL SYSTEMS. When this is the case, other relevant standards also apply.

EXAMPLE 1 MULTIFUNCTION PATIENT MONITOR incorporated into a critical care ventilator where ISO 80601-2-12 also applies.

EXAMPLE 2 MULTIFUNCTION PATIENT MONITOR incorporated into a homecare ventilator for dependent PATIENT where ISO 80601-2-72 also applies.

EXAMPLE 3 MULTIFUNCTION PATIENT MONITOR incorporated into anesthetic workstation where ISO 80601-2-13 also applies.

EXAMPLE 4 MULTIFUNCTION PATIENT MONITOR incorporated into haemodialysis equipment, IEC 60601-2-16 also applies.

This document does not apply to implantable parts of MULTIFUNCTION PATIENT MONITORS.