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 (ISO 80601-2-61: 2017) " الأجهزة الكهربائية الطبية-الجزء 2-61: المتطلبات الخاصة للسلامة والأداء الأساسيين لأجهزة مقياس الأكسجين النبضي "، 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. (ISO 80601-2-61: 2017" Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment" 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 document applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of PULSE OXIMETER EQUIPMENT intended for use on humans, hereafter referred to as ME EQUIPMENT. This includes any part necessary for NORMAL USE, including the PULSE OXIMETER MONITOR, PULSE OXIMETER PROBE, and PROBE CABLE EXTENDER.

These requirements also apply to PULSE OXIMETER EQUIPMENT, including PULSE OXIMETER MONITORS, PULSE OXIMETER PROBES and PROBE CABLE EXTENDERS, which have been REPROCESSED.

The intended use of PULSE OXIMETER EQUIPMENT includes, but is not limited to, the estimation of arterial oxygen haemoglobin saturation and pulse rate of PATIENTS in professional healthcare institutions as well as PATIENTS in the HOME HEALTHCARE ENVIRONMENT and the EMERGENCY MEDICAL SERVICES ENVIRONMENT.

This document is not applicable to PULSE OXIMETER EQUIPMENT intended for use in laboratory research applications nor to oximeters that require a blood sample from the PATIENT.

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 document are not covered by specific requirements in this document except in 201.11 and in 7.2.13 and

8.4.1 of the general standard.

NOTE 1 See also 4.2 of the general standard. “The general standard” is IEC 60601-1:2005+AMD1:2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

This document can also be applied to ME EQUIPMENT and their ACCESSORIES used for compensation or alleviation of disease, injury or disability.

This document is not applicable to PULSE OXIMETER EQUIPMENT intended solely for foetal use.

This document is not applicable to remote or slave (secondary) equipment that displays SpO2 values that are located outside of the PATIENT ENVIRONMENT.

NOTE 2 ME EQUIPMENT that provides selection between diagnostic and monitoring functions is expected to meet the requirements of the appropriate document when configured for that function.

This document is applicable to PULSE OXIMETER EQUIPMENT intended for use under extreme or uncontrolled environmental conditions outside the hospital environment or physician's office, such as in ambulances and air transport. Additional standards can apply PULSE OXIMETER EQUIPMENT for those environments of use.

This document is a particular standard in the IEC 60601-1 and ISO/IEC 80601 series of standards.