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 121) " فريق عمل مواصفات أجهزة التخدير والتنفس " بتبني المواصـــفة الدولية رقم (ISO 80601-2-70:2015) "الأجهزة الطبية الكهربائية –الجزء 2-70: المتطلبات العامة للسلامة والأداء الأساسيين لأجهزة علاج توقف التنفس أثناء النوم"، والتي أصدرتها "المنظمة الدولية للتقييس" 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/TC 121) ‘‘Anaesthetic and respiratory equipment ’’ has adopted the International Standard No.(ISO 80601-2-70:2015) ‘‘ Medical Electrical Equipment -- Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment ", issued by ‘‘ International Organization for Standardization’’ in its original language. This standard is identically adopted without modifications in its original language and has been approved as national standard by SFDA board of directors in its meeting No ( ) Held on (/ / AH), agreed with (/ / G).

Scope

ISO 80601-2-70:2015 is applicable to the basic safety and essential performance of sleep apnoea breathing therapy equipment, hereafter referred to as me equipment, intended to alleviate the symptoms of patients who suffer from obstructive sleep apnoea by delivering a therapeutic breathing pressure to the respiratory tract of the patient. Sleep apnoea breathing therapy equipment is intended for use in the home healthcare environment by lay operators as well as in professional healthcare institutions.

It excludes sleep apnoea breathing therapy equipment intended for use with neonates.

ISO 80601-2-70:2015 is applicable to me equipment or an me system intended for those patients who are not dependent on mechanical ventilation.

ISO 80601-2-70:2015 is not applicable to me equipment or an me system intended for those patients who are dependent on mechanical ventilation such as patients with central sleep apnoea.

ISO 80601-2-70:2015 is also applicable to those accessories intended by their manufacturer to be connected to sleep apnoea breathing therapy equipment, where the characteristics of those accessories can affect the basic safety or essential performance of the sleep apnoea breathing therapy equipment.