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 سواء كانت مستوردة أو مصنعة محلياً، وقد قام قطاع الأجهزة و المنتجات الطبية بالهيئة ضمن برنامج عمل فريق العمل رقم (SFDA/MDS/TC 121) " فريق عمل مواصفات أجهزة التخدير والتنفس " بتبني المواصفة الدولية رقم (ISO 80601-2-79:2018) " الأجهزة الكهربائية الطبية – الجزء 2-79: المتطلبات الخاصة للسلامة والأداء الأساسيين لأجهزة دعم التنفس للمصابين بضعف بالجهاز التنفسي " ، والتي أصدرتها " المنظمة الدولية للتقييس " 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 (.....) و تاريخ .....

Foreword

The Saudi Food & Drug Authority is an independent organization mainly responsible for regulating imported/locally produced food, drug and medical devices, which includes, inter alia, setting their standards.

(Medical electrical equipment -- Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment), issued by (International Organization for Standardization), has been adopted identically in its original language as a national standard and approved by SFDA CEO decision No (…) on (date)

Scope

This document applies to the basic safety and essential performance of ventilatory support equipment, as defined in 201.3.205, for ventilatory impairment, as defined in 201.3.202, hereafter also referred to as me equipment, in combination with its accessories:

— intended for use in the home healthcare environment;

— intended for use by a lay operator; and

— intended for use with patients who have ventilatory impairment, the most fragile of these patients, would not likely experience injury with the loss of this artificial ventilation; and

— not intended for patients who are dependent on artificial ventilation for their immediate life support.

EXAMPLE 1 Patients with mild to moderate chronic obstructive pulmonary disease (COPD).

NOTE 1 In the home healthcare environment, the supply mains is often not reliable.

NOTE 2 Such ventilatory support equipment can also be used in non-critical care applications of professional health care facilities.

This document is also applicable to those accessories intended by their manufacturer to be connected to the breathing system of ventilatory support equipment for ventilatory impairment, where the characteristics of those accessories can affect the basic safety or essential performance of the ventilatory support equipment for ventilatory impairment.

EXAMPLE 2 Breathing sets, connectors, water traps, expiratory valve, humidifier, breathing system filter, external electrical power source, distributed alarm system.

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 IEC 60601-1:2005+AMD1:2012, 7.2.13 and 8.4.1.

NOTE 3 Additional information can be found in IEC 60601-1:2005+AMD1:2012, 4.2.

This document does not specify the requirements for:

— ventilators or accessories for ventilator-dependent patients intended for critical care applications, which are given in ISO 80601-2-12;

— ventilators or accessories intended for anaesthetic applications, which are given in ISO 80601-2-13[4];

— ventilators or accessories intended for the emergency medical services environment, which are given in ISO 80601-2-84 [5] [1], the future replacement for ISO 10651-3[6];

— ventilators or accessories intended for ventilator-dependent patients in the home healthcare environment, which are given in ISO 80601-2-72;

— ventilatory support equipment or accessories intended for ventilatory insufficiency, which are given in ISO 80601-2-80[1];

— sleep apnoea therapy me equipment, which are given in ISO 80601-2-70[7];

— continuous positive airway pressure (CPAP) me equipment;

— high-frequency jet ventilators (HFJVs);

— high-frequency oscillatory ventilators (HFOVs)[8];

— oxygen therapy constant flow me equipment;

— cuirass or "iron-lung" ventilation equipment.

This document is a document in the IEC 60601 and IEC/ISO 80601 series of documents.

[1] Under preparation. Stage at the time of publication: ISO/DIS 80601-2-84:2017