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 18562-2:2017) "تقييم التوافق الحيوي لمجاري غازات التنفس في تطبيقات الرعاية الصحية –الجزء 2: اختبارات الانبعاثات من الجسيمات "، 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 18562-2:2017) " Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 2: Tests for emissions of particulate matter", 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 18562-2:2017 specifies tests for the emissions of particulate matter from the gas pathways of a medical device, its parts or accessories, which are intended to provide respiratory care or supply substances via the respiratory tract to a patient in all environments. The tests of this document are intended to quantify particles from 0,2 µm diameter to 10 µm diameter that are emitted by the medical device, its parts or accessories into the respirable gas stream. This document establishes acceptance criteria for these tests. This document does not address nanoparticles. Insufficient data exist to establish exposure limits for particles less than 0,2 µm in diameter.

NOTE 1 Smaller and larger particles could also present biological hazards, and additional information outside the scope of this document can be needed to meet requirements of some authorities having jurisdiction.

ISO 18562-2:2017 therefore adopts the same approach as the US Environmental Protection Agency (EPA) in setting limits based solely on particle size and not their chemistry.

ISO 18562-2:2017 addresses potential contamination of the gas stream arising from the gas pathways, which is then conducted to the patient.

ISO 18562-2:2017 applies over the expected service life of the medical device in normal use and takes into account the effects of any intended processing or reprocessing.

ISO 18562-2:2017 does not address biological evaluation of the surfaces of gas pathways that are in direct contact with the patient. The requirements for direct contact surfaces are found in the ISO 10993 series.

Medical devices, parts or accessories, containing gas pathways that are addressed by this document, include, but are not limited to, ventilators, anaesthesia workstations (including gas mixers), breathing systems, oxygen conserving devices, oxygen concentrators, nebulizers, low-pressure hose assemblies, humidifiers, heat and moisture exchangers, respiratory gas monitors, respiration monitors, masks, mouth pieces, resuscitators, breathing tubes, breathing systems filters, Y-pieces, and any breathing accessories intended to be used with such devices. The enclosed chamber of an incubator, including the mattress, and the inner surface of an oxygen hood are considered to be gas pathways and are also addressed by this document.

ISO 18562-2:2017 does not address contamination already present in the gas supplied from the gas sources while medical devices are in normal use.

EXAMPLE Contamination arriving at the medical device from gas sources such as medical gas pipeline systems (including the non-return valves in the pipeline outlets), outlets of pressure regulators connected or integral to a medical gas cylinder, or room air taken into the medical device is not addressed by ISO 18562 (all parts).

NOTE 2 This document has been prepared to address the relevant essential principles of safety and performance as indicated in Annex B.