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 18562-1:2017) "تقييم التوافق الحيوي لمسارات غازات التنفس في تطبيقات الرعاية الصحية –الجزء 1: التقييم والاختبار ضمن عمليات إدارة المخاطر " 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 18562-1:2015) " Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process ", issued by “ International Organization for Standardization” in its original language. This standard is identically adopted 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

This document specifies:

- — the general principles governing the biological evaluation within a RISK MANAGEMENT PROCESS of 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 general categorization of GAS PATHWAYS based on the nature and duration of their contact with the gas stream;
- — the evaluation of existing relevant data from all sources;
- — the identification of gaps in the available data set on the basis of a RISK ANALYSIS;
- — the identification of additional data sets necessary to analyse the biological safety of the GAS PATHWAY;
- — the assessment of the biological safety of the GAS PATHWAY.

This document covers general principles regarding BIOCOMPATIBILITY assessment of MEDICAL DEVICE materials, which make up the GAS PATHWAY, but does not cover biological HAZARDS arising from any mechanical failure, unless the failure introduces a toxicity RISK (e.g. by generating PARTICULATES). The other parts of ISO 18562 cover specific tests that address potentially hazardous substances that are added to the respirable gas stream and establish acceptance criteria for these substances.
This document addresses potential contamination of the gas stream arising from the GAS PATHWAYS within the MEDICAL DEVICE, which might then be conducted to the PATIENT.

This document 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.

This document does not address biological evaluation of the surfaces of MEDICAL DEVICES 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 equipment, oxygen concentrators, nebulizers, low-pressure hose assemblies, humidifiers, heat and moisture exchangers, respiratory gas monitors, respiration monitors, masks, mouth pieces, resuscitators, breathing tubes, breathing system filters and Y-pieces as well as any breathing ACCESSORIES intended to be used with such MEDICAL 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.

This document 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).

Future parts might be added to address other relevant aspects of biological testing including additional contamination that might arise from the GAS PATHWAY because of the presence of drugs and anaesthetic agents added to the gas stream.

NOTE 1 Some AUTHORITIES HAVING JURISDICTION require evaluation of these RISKS as part of a biological evaluation.

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