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 198) " فريق عمل مواصفات تعقيم منتجات الرعاية الصحية " بتبني المواصـــــــفة الدولية رقم (ISO/TS 19930:2017) " الدليل الإرشادي المبني على المخاطر لضمان تعقيم المنتج الطبي ذو الإستخدام الواحد بشكله النهائي المغلف الذي لا يتحمل المعالجة لضمان لتحقيق أقصى مستوى من ضمان التعقيم 10-6"، 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 198) “Sterilization of health care products” has adopted the International Standard No. (ISO/TS 19930:2017) “Guidance on aspects of a risk-based approach to assuring sterility of terminally sterilized, single-use health care product that is unable to withstand processing to achieve maximally a sterility assurance level of 10-6” 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 (../../14..AH), agreed with (../../20.. G).

Scope:

This document provides guidance on identifying the aspects to be considered as part of a risk-based approach to selecting a sterility assurance level (SAL) for terminally sterilized, single-use health care product that is unable to withstand processing to achieve maximally a SAL of 10−6.

In addition, this document provides

a) background information on the assurance of sterility and sterility assurance level, and

b) guidance on strategies that can allow the achievement of a maximal SAL of 10−6.

This document describes the elements of a quality management system which are applied to enable the appropriate selection of a SAL for terminally sterilized, single-use health care product that is unable to withstand processing to achieve maximally a SAL of 10−6.

NOTE It is not a requirement of the International Standards for development, validation and routine control of a sterilization process to have a full quality management system. Attention is drawn to the standard for quality management systems (see ISO 13485) that controls all stages of the lifecycle of health care product.

This document is applicable to sterilization processes in which microorganisms are inactivated by physical and/or chemical means.

This document does not apply

— to selecting a maximal SAL greater than 10−6 for health care product that is able to withstand processing to achieve maximally a SAL of 10−6;

— in cases where a maximal SAL of 10−6 is required and an alternative SAL is not allowed;

— in cases where a maximal SAL of greater than 10−6 (e.g. 10−3) has been accepted by regulatory authorities within their jurisdiction for health care product for defined use;

— to the sterilization of used or reprocessed health care product;

— to sterilization of health care product by filtration.

This document does not describe detailed procedures for assessing microbial inactivation.

This document does not specify requirements for the development, validation and routine control of a process for inactivating the causative agents of spongiform encephalopathies such as scrapie, bovine spongiform encephalopathy and Creutzfeldt-Jakob disease. Specific recommendations have been produced in particular countries for the processing of materials potentially contaminated with these agents.

NOTE See also ISO 22442-1, ISO 22442-2 and ISO 22442-3.

This document does not supersede or modify published International Standards for particular sterilization processes.

This document neither recommends a SAL for a given health care product nor identifies a maximal SAL for a health care product to be labelled “sterile”.

NOTE These are matters for regulatory authorities and can vary from country to country.