

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 سواء كانت مستوردة أو مصنعة محلياً بواسطة لجان فنية متخصصة، وقد قام قطاع الأجهزة والمنتجات الطبية بالهيئة ضمن برنامج عمل الفريق رقم (SFDA/MDS/TC 84) "فريق عمل مواصفات الأجهزة الطبية لحقن/إدخال المنتجات العلاجية والقساطر في جسم الانسان" بتبني المواصفة الدولية رقم (ISO 7886-4:2018) "الحقن المعقمة المستخدمة تحت الجلد المستخدمة لمرة واحدة - الجزء 4: الحقن بخاصية منع إعادة استخدام الحقن"، والتي أصدرتها "المنظمة الدولية للتقييس" وذلك بلغتها الأصلية. وقد اعتمدت هذه المواصفة كمواصفة سعودية متبناة بالتعديل بلغتها الأصلية وذلك في اجتماع مجلس الإدارة رقم (..) والذي عقد بتاريخ (..../1440 هـ) الموافق (../2019 م).

- التعديلات مشار إليها في ملحق التعديلات.

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 84) "Devices for administration of medicinal products and catheters" has adopted the International Standard No. (ISO 7886-4:2018) "Sterile hypodermic syringes for single use -- Part 4: Syringes with re-use prevention feature" issued by "International Organization for Standardization" in its original language. This standard is adopted with modifications in its original language and has been approved as national standard by SFDA board of directors in its meeting No (..) Held on (../1440 AH), agreed with (../2019 G).

- The modifications are mentioned in the Modifications Annex.

Scope

This document specifies requirements for sterile single-use hypodermic syringes made of plastic and rubber materials with or without needle, and intended for the aspiration of fluids or for the injection of fluids immediately after filling and of design such that the syringe can be rendered unusable after use.

This document is not applicable to syringes made of glass [specified in ISO 595 (withdrawn)], auto-disable syringes for fixed dose immunization (ISO 7886-3) and syringes designed to be pre-filled. It does not address compatibility with injection fluids. Other standards can be applicable when syringes are used for any other intended purpose than those specified in this document.

NOTE Syringes designed to reduce the risk of needle-stick injuries can also comply with this document with regard to their re-use prevention properties, but it is stressed that anti-needle-stick properties of syringes are not in themselves addressed in this document.

ملحق التعديلات
Modifications Annex

Project: SFDA.MD.84.DS.ISO 7886-4:2018

#	رقم الصفحة Page No.	رقم البند/البند الفرعي Clause/Subclause No.	رقم السطر Line No.	فقرة/صورة/جدول Paragraph/ Figure/ Table/	نوع الملاحظة Comment type	الملاحظات Comments	التعديل Modification
1	2	3.3			te	This documents does not address auto disable syringes, using this description will be confusing	Modify: 3.3 auto disabled reuse prevention feature
2	2	3.3			te	Activation of the reuse prevention feature could be prior or at end of injection	Modify: feature that automatically activates, prior to or at end of injection, to render the syringe unusable by the delivery of the intended dosage
3	2	3.3			te	This documents does not address auto disable syringes, using this description will be confusing	Modify: 4.2 Types of re-use prevention feature The re-use prevention feature shall be either: — Type 1: auto disabled reuse prevention feature;
4	5	14.1			te	Sometimes there may be an urgent need for the user to contact the manufacturer to receive some information about the product	Modify: The information shall include the identity and the contact information of the manufacturer.

Comment type: ge = general te = technical ed = editorial