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 84) " فريق عمل مواصفات الأجهزة الطبية لحقن/إدخال المنتجات العلاجية والقساطر في جسم الانسان " بتبني المواصفة الدولية رقم (ISO 8537:2016) "الحقن المعقمة ذات الاستخدام لمرة واحدة، مع أو بدون الإبر، للأنسولين"، 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 (../../..14 هـ) الموافق (../../..20 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 8537:2016) "Sterile single-use syringes, with or without needle, for insulin", 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 (/ / AH), agreed with (/ / G).

- The modifications are mentioned in the Modifications Annex.

Scope

This International Standard specifies requirements and test methods for empty, sterile, single-use syringes, with or without needles, made of plastic materials and intended solely for the injection of insulin, with which the syringes are filled by the end user. This International Standard covers syringes intended for single-use only in humans and with insulins of various concentrations.

The insulin syringes specified in this International Standard are intended for use (i.e. insulin injection) immediately after filling and are not intended to contain insulin for extended periods of time.

This International Standard excludes single-use syringes made of glass, syringes for use with power driven syringe pumps, syringes that are pre-filled by the manufacturer, and syringes intended to be stored after filling (e.g. in a kit intended for filling by a pharmacist).

ملحق التعديلات
Modifications Annex

Project: SFDA.MD.84.DS.ISO 8537:2016

#	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	Page 1	2 Normative References			ge	Standard: ISO 594-1 Has been deleted and replaced with: ISO 80369-7:2016	Replace the referenced standards with: ISO 80369-7:2016 And delete the footer note.
2	Page 1	2 Normative References			ge	Standard: ISO 15223-1:2012 Has been updated to: ISO 15223-1:2016	ISO 15223-1:~~2012~~ 2016
3	Page 6	5.2			ge	The word "fabrication" should be replaced with the term "construction" which is more positive word	- materials used for ~~fabrication~~ construction of the syringe barrel … - materials used for ~~fabrication~~ construction of syringes and needles …

4	Page 7	5.4.2			ge	The sentence "syringe assessment fluid" should be replaced with the phrase " syringe extraction fluid" which is more authentic	The results shall show that the pH value of the syringe ~~assessment~~ extraction fluid is within one pH unit
5	Page 8	5.5.2			te	The subclause title: "Lubrication of needle tube" should be replaced as: "Lubrication of syringes and needle tube" as syringes also need to be lubricate	5.5.2 Lubrication of syringes and needle tube
6	Page 8	5.5.2			te		If the ~~needle tube is~~ interior surface of the syringe, including the piston and the exterior surface of the needle tube are lubricated, the lubricant shall ~~not be visible to an individual with normal or corrected-to-normal vision as droplets of fluid on the outside surfaces of the needle tube~~ form pools of fluid on the interior surface of the syringe nor drops on the exterior surface of the needle tube or in the bore.

7	Page 8	**5.**8.1			ge	Standard: ISO 594-1 Has been deleted and replaced with: ISO 80369-7:2016	The male conical fitting of the syringe nozzle on syringe types 1, 2, 3 and 4 shall comply with the requirements of ~~ISO 594-1~~ ISO 80369-7.
8	Page 9	5.11.1			te	The devices are intended to use after sterilization only hence there is no chance of transmission of infectious agents	Dead space should be minimized to reduce waste ~~and transmission of infectious agents~~ of medications
9	Page 12	7.2.2			ge	Standard: ISO 15223-1:2012 Has been updated to: ISO 15223-1:2016	in accordance with ISO 15223-1:~~2012~~ 2016
10	Page 12	7.2.2 Note 1			ge	Standard: ISO 15223-1:2012 Has been updated to: ISO 15223-1:2016	See ISO 15223-1:~~2012~~ 2016
11	Page 12	7.2.2 b)			te	Indication of the "manufacturer" in the marking is mandatory according to SFDA MDMA requirements	the name and/or trade-mark of the manufacturer ~~or~~ and authorized representative; if applicable

12	Page 12	7.2.3			ge	Standard: ISO 15223-1:2012 Has been updated to: ISO 15223-1:2016	in accordance with ISO 15223-1:~~2012~~ 2016
13	Page 12	7.3 Notes 1,2,3, 4 & 5			ge	Standard: ISO 15223-1:2012 Has been updated to: ISO 15223-1:2016	See ISO 15223-1:~~2012~~ 2016
14	Page 12	7.3 f)			te	Indication of the "manufacturer" in the marking is mandatory according to SFDA MDMA requirements	the name and/or trade-mark of the manufacturer ~~or~~ and authorized representative; if applicable
15	Page 12	7.4			ge	Standard: ISO 15223-1:2012 Has been updated to: ISO 15223-1:2016	in accordance with ISO 15223-1:~~2012~~ 2016
16	Page 13	7.3 Notes 1,2,3, 4 & 5			ge	Standard: ISO 15223-1:2012 Has been **updated** to: ISO 15223-1:2016	See ISO 15223-1:~~2012~~ 2016

17	Page 13	7.4 d)			te	Indication of the "manufacturer" in the marking is mandatory according to SFDA MDMA requirements	the name and/or trade-mark of the manufacturer ~~or~~ and authorized representative; if applicable
18	Page 13	7.5			ge	Standard: ISO 15223-1:2012 Has been **updated** to: ISO 15223-1:2016	in accordance with ISO 15223-1:~~2012~~ 2016
19	Page 13	7.5 Notes 1,2,3, 4, 5 & 6			ge	Standard: ISO 15223-1:2012 Has been **updated** to: ISO 15223-1:2016	See ISO 15223-1:~~2012~~ 2016
20	Page 13	7.5 f)			te	Indication of the "manufacturer" in the marking is mandatory according to SFDA MDMA requirements	the name and/or trade-mark of the manufacturer ~~or~~ and authorized representative; if applicable
21	Page 14	7.6			ge	Standard: ISO 15223-1:2012 Has been **updated** to: ISO 15223-1:2016	in accordance with ISO 15223-1:~~2012~~ 2016

22	Page 14	7.6 Notes 1,2,3, 4 & 5			ge	Standard: ISO 15223-1:2012 Has been **updated** to: ISO 15223-1:2016	See ISO 15223-1:~~2012~~ 2016
23	Page 14	7.6 d)			te	Indication of the "manufacturer" in the marking is mandatory according to SFDA MDMA requirements	the name and/or trade-mark of the manufacturer ~~or~~ and authorized representative; if applicable

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