

## 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 والقسطر في جسم الانسان " بتبني المواصفة الدولية رقم (ISO 9626:2016) "أنبوب الإبرة الفولاذي المقاوم للصدأ لتصنيع الأجهزة الطبية - المتطلبات وطرق الاختبار"، 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 9626:2016) "Stainless steel needle tubing for manufacture of medical devices — Requirements and test methods", 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 applies to rigid stainless steel needle tubing suitable for use in the manufacture of hypodermic needles and other medical devices primarily for human use.

This International Standard provides requirements and test methods for the tubes manufactured for needles as component used in medical devices. Additional performance testing on the tube aspect may be required when the component is incorporated in the ready-to-use device.

This International Standard specifies the dimensions and mechanical properties of steel tubing of designated metric sizes 3,4 mm (10 Gauge) to 0,18 mm (34 Gauge).

It does not apply to flexible stainless steel tubing because the mechanical properties differ from those specified for rigid tubing in this International Standard. However, manufacturers and purchasers of flexible tubing are encouraged to adopt the dimensional specifications given in this International Standard.

ملحق التعديلات  
Modifications Annex

Project: SFDA.MD.84.DS.ISO 9626:2016

#	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		Standard's Title			ed		Stainless steel needle tubing for <del>the</del> manufacture of medical devices - Requirements and test methods
2	Page 1	3 Terms and definitions			ge	No need to numerate single note	Note 4 to entry: It is expressed in millimetres
3	Page 1	3 Terms and definitions			ge	No need to numerate single note	Note 4 to entry: A particular gauge size corresponds to a designated metric size...
4	Page 1	3 Terms and definitions			ge	No need to numerate single note	Note 4 to entry: It is expressed as RW=Regular Wall, TW=Thin Wall,
5	Page 2	5.2	1		ed	All other similar standards use the term "corrected to normal"	When examined by normal or corrected to <b>normal</b> vision

6	Page 2	5.2	5		ed	All other similar standards use the term "corrected to normal"	When examined by normal or corrected to normal vision
7	Page 2	5.3	1		ed	All other similar standards use the term "corrected to normal"	When examined by normal or corrected to normal vision
8	Page 7	5.9	2		ed	All other similar standards use the term "corrected to normal"	When examined by normal or corrected to normal vision

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

