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 210) " فريق عمل مواصفات إدارة جودة الأجهزة الطبية " بتبني المواصـــفة الدولية رقم (ISO 16142-1:2016) " الأجهزة الطبية – المبادئ الأساسية المعترف بها للسلامة والأداء للأجهزة الطبية – الجزء 1: المبادئ الأساسية العامة والمبادئ الإضافية المحددة لكافة الأجهزة الطبية الغير مخبرية وإرشادات اختيار المواصفات القياسية "، 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 210) “Quality management and corresponding general aspects for medical devices” has adopted the International Standard No.(ISO 16142-1:2016) " Medical devices -- Recognized essential principles of safety and performance of medical devices -- Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards", 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 part of ISO 16142, which includes the essential principles of safety and performance, identifies significant standards and guides that can be used in the assessment of conformity of a medical device to the recognized essential principles that when met, indicate a medical device is safe and performs as intended. This part of ISO 16142 identifies and describes the six general essential principles of safety and performance that apply to all medical devices, including IVD medical devices (*in vitro* diagnostic).

This part of ISO 16142 also identifies and describes the additional essential principles of safety and performance which need to be considered during the design and manufacturing process, which are relevant to medical devices other than IVD medical devices. Future ISO 16142-2 is intended to identify and describe the essential principles of safety and performance, which need to be considered during the design and manufacturing process of IVD medical devices.

NOTE During the design process, the manufacturer selects which of the listed design and manufacturing principles apply to the particular medical device and documents the reasons for excluding others.

This part of ISO 16142 is intended for use as guidance by medical device manufacturers, standards development organizations, authorities having jurisdiction, and conformity assessment bodies.