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 150) " فريق عمل مواصفات الأجهزة الطبية المزروعة" بتبني المواصفة الدولية رقم (ISO 14708-2:2012) " الأجهزة المزروعة جراحياً – الأجهزة الطبية النشطة المزروعة – الجزء 2: منظمات ضربات القلب" ، والتي أصدرتها "المنظمة الدولية للتقييس" وذلك بلغتها الأصلية. وقد اعتمدت هذه المواصفة كمواصفة سعودية متبناة بالتعديل بلغتها الأصلية وذلك في اجتماع مجلس الادارة رقم ( ) والذي عقد بتاريخ (../../..14 هـ) الموافق (../../..20م).

- التعديلات مشار إليها في ملحق التعديلات.

Foreword

Saudi Food and Drug Authority (SFDA) is an independent organization with 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 150) “Implants for surgery” has adopted the International Standard No.(ISO 14708-2:2012) “Implants for surgery -- Active implantable medical devices -- Part 2: Cardiac pacemakers”, issued by “International Organization for Standardization” in its original language. This standard is adopted identically 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 part of ISO 14708 specifies requirements that are applicable to those active implantable medical devices intended to treat bradyarrhythmias.

The tests that are specified in this part of ISO 14708 are type tests, and are to be carried out on samples of a device to show compliance.

This part of ISO 14708 is also applicable to some non-implantable parts and accessories of the devices (see NOTE 1.(

The electrical characteristics of the implantable pulse generator or lead are determined either by the appropriate method detailed in this particular standard or by any other method demonstrated to have an accuracy equal to, or better than, the method specified. In case of dispute, the method detailed in this particular standard applies.

Any features of an active implantable medical device intended to treat tachyarrhythmias are covered by ISO 14708-6.

NOTE 1 The device that is commonly referred to as an active implantable medical device may in fact be a single device, a combination of devices, or a combination of a device or devices and one or more accessories. Not all of these parts are required to be either partially or totally implantable, but there is a need to specify some requirements of non-implantable parts and accessories if they could affect the safety or performance of the implantable device.

NOTE 2 In this part of ISO 14708, terms printed in small capital letters are used as defined in Clause 3. Where a defined term is used as a qualifier in another term, it is not printed in small capital letters unless the concept thus qualified is also defined.

ملحق التعديلات
Modifications Annex

Project: SFDA.MD.150.DS.ISO 14708-2:2012

#	رقم الصفحة Page No.	رقم البند/البند الفرعي Clause/Sub clause No.	رقم السطر Line No.	فقرة/ صورة/ جدول Paragraph/ Figure/ Table/	نوع الملاحظة Comment type	الملاحظات Comments	التعديل Modification
1	1	1			ed	It is preferable to identify the audience	This part of ISO 14708 is a guidance for industry specifies….

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