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) " الأجهزة الطبية النشطة القابلة للزراعة – نظام التوصيل رباعي الأقطاب للأجهزة المنظمة لضربات القلب القابلة لزراعة – الأبعاد وطرق الاختبار" ، والتي أصدرتها "المنظمة الدولية للتقييس" وذلك بلغتها الأصلية. وقد اعتمدت هذه المواصفة كمواصفة سعودية متبناة بالمطابقة بلغتها الأصلية وذلك في اجتماع مجلس الادارة رقم ( ) والذي عقد بتاريخ (../../..14 هـ) الموافق (../../..20م).

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 27186:2010) “Active implantable medical devices -- Four-pole connector system for implantable cardiac rhythm management devices - Dimensional and test requirements”, 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).

Scope

This International Standard specifies a four-pole connector system for implantable cardiac rhythm management devices which have pacing, electrogram sensing and/or defibrillation functions. This International Standard includes requirements for the connector portion of an implantable lead as well as for the mating connector cavity attached to an implantable pulse generator. Essential dimensions and performance requirements are specified together with appropriate test methods.

This International Standard is not intended to replace or provide alternatives for unipolar or bipolar connector standards that currently exist (such as ISO 11318 and ISO 5841-3). This International Standard is not applicable to high voltage systems with intended outputs greater than 1 000 V and/or 50 A. This International Standard is not applicable to systems which include sensors or unique electrodes that are not capable of conventional pacing, electrogram sensing and/or defibrillation functions.

This International Standard does not specify all connector features. It does not address all aspects of functional compatibility, safety or reliability of leads and pulse generators assembled into a system.

NOTE Lead and pulse generator connector systems not conforming to this International Standard might be safe and reliable, and might have clinical advantages.