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 المواصفة الدولية رقم (ISO 80369-6:2016) " الوصلات صغيرة الثقوب للسوائل والغازات في تطبيقات الرعاية الصحية– الجزء 6: وصلات لتطبيقات الجهاز العصبي "، 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 80369-6:2016) " Small bore connectors for liquids and gases in healthcare applications - Part 6: Connectors for neuraxial applications ", 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

ISO 80369-6:2016 specifies requirements for small-bore connectors intended to be used for connections in neuraxial applications. Neuraxial applications involve the use of medical devices intended to administer medications to neuraxial sites, wound infiltration anaesthesia delivery, and other regional anaesthesia procedures or to monitor or remove cerebro-spinal fluid for therapeutic or diagnostic purposes.

NOTE 1 Sites for the neuraxial application include the spine, intrathecal or subarachnoid space, ventricles of the brain, and the epi-, extra-, or peri-dural space. Neuraxial application anaesthetics can be administered regionally affecting a large part of the body, such as a limb, and include plexus blocks, such as the branchial plexus blocks or single nerve blocks. Neuraxial application procedures include continuous infusion of wounds with local anaesthetic agents.

NOTE 2 For the purposes of this part of ISO 80369, local anaesthesia injected hypodermically is not considered a neuraxial application.

EXAMPLES Intended administration includes intrathecal chemotherapy, local anaesthetics, radiological contrast agents, antibiotics, analgesics.

This part of ISO 80369 specifies dimensions and requirements for the design and functional performance of these small-bore connectors intended to be used with medical devices.

This part of ISO 80369 does not specify requirements for the medical devices or accessories that use these connectors. Such requirements are given in particular International Standards for specific medical devices or accessories.

NOTE 3 Manufacturers are encouraged to incorporate the small-bore connectors specified in this part of ISO 80369 into medical devices, medical systems, or accessories, even if currently not required by the relevant particular medical device standards. It is expected that when the relevant particular medical device standards are revised, requirements for small-bore connectors, as specified in this part of ISO 80369, will be included. Furthermore, it is recognized that standards need to be developed for many medical devices used for neuraxial applications.

NOTE 4 ISO 80369-1:2010, 5.8, specifies alternative methods of compliance with ISO 80369-1:2010, for small-bore connectors intended for use with neuraxial application medical devices or accessories, which do not comply with this part of ISO 80369.