

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 80369-3:2016) " الوصلات صغيرة الثقوب للسوائل والغازات في تطبيقات الرعاية الصحية- الجزء 3: وصلات للتطبيقات المعوية "، 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 80369-3:2016) " Small-bore connectors for liquids and gases in healthcare applications -- Part 3: Connectors for enteral 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 80369-3:2016 specifies the dimensions and requirements for the design and functional performance of small-bore connectors intended to be used for connections on enteral medical devices and accessories.

NOTE 1 Enteral medical devices include enteral feeding sets, enteral drainage sets, enteral syringes, and patient interface devices including access ports.

It does not specify the dimensions and 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.

It does not specify requirements for small-bore connectors that are used for the following:

- gastric suction-only medical devices;
- oral-only medical devices;

EXAMPLE An oral tip syringe that is not intended to connect to another medical device. It is intended to administer directly to the patient's mouth.

- pressurizing and depressurizing the retention mechanism (e.g. balloon) used to hold invasive enteral medical devices in place;
- medical devices for rectal drainage, rectal administration of medicines or fluid, and any other rectal access medical device;
- gastrointestinal endoscopy equipment;
- skin level gastrostomy medical devices.

NOTE 2 Manufacturers are encouraged to incorporate the small-bore connectors specified in ISO 80369-3 :2016 into enteral medical devices 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 ISO 80369, will be included.