

## 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 سواء كانت مستوردة أو مصنعة محلياً بواسطة لجان فنية متخصصة، وقد قام قطاع الأجهزة والمنتجات الطبية بالهيئة ضمن برنامج عمل الفريق رقم (SFDA/MDS/TC 173) "فريق عمل مواصفات أجهزة ومنتجات ذوي الاحتياجات الخاصة" بتبني المواصفة الدولية رقم (ISO 17966:2016) "المنتجات المساعدة على النظافة الشخصية والداعمة للمستخدمين - المتطلبات وطرق الاختبار"، 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 ( / / ١٤٠٠ هـ ) الموافق ( / / ٢٠٠٠ 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 173) "Assistive products" has adopted the International Standard No. (ISO 17966:2016) "Assistive products for personal hygiene that support users -- Requirements and test methods" 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 ( / / 14..AH), agreed with ( / / 20.. G).

## Scope

This International Standard specifies requirements and associated test methods for assistive products for personal hygiene (APPHs) that support users and which are intended by the manufacturer to alleviate or compensate for disability. The work environment and safety aspects for assistants are also included. It specifies safety and performance requirements that apply during normal use and foreseeable misuse and failure. It also specifies methods of measurement of the forces necessary to operate controls and specifies limits on the forces needed for some operations.

This International Standard specifies requirements and test methods for assistive products within the following divisions of ISO 9999:2011:

09 12 03 Commode chairs;

NOTE This covers mobile and static products.

09 12 06 Toilets with built in raising and height adjustable mechanism;

NOTE This excludes toilets with built-in douche and air dryers.

09 12 09 Toilet seats;

09 12 12 Raised toilet seats mounted on frame;

09 12 15 Toilet seats inserts;

09 12 18 Raised toilet seats fixed to toilet;

09 12 21 Toilet seats with built-in raising mechanism to help standing up and sitting down;

09 12 24 Toilet arm supports and toilet back supports mounted on toilet;

09 12 25 Toilet arm supports and toilet back supports, free standing;

09 12 36 Douches and air dryers for attachment to a toilet;

09 33 03 Bath/shower chairs (with and without wheels), bath boards, stools, back supports and seats;

09 33 12 Bathing stretchers, shower tables and diaper-changing tables;

18 15 06 Height adjustable plinths and brackets;

NOTE Refers to height adjustable plinths and brackets when used as an assistive product for personal hygiene (APPH). Height adjustable mechanisms for other items such as basins may be included.

18 18 03 Handrails and support rails;

18 18 06 Fixed grab bars and handgrips;

18 18 10 Removable grab rails and handgrips;

NOTE This excludes removable grab rails and handgrips which are static as defined in 3.27.

18 18 11 Hinged rails and arm supports;

This International Standard does not encompass requirements regarding:

- safe mounting in building structures;
- requirements regarding fixed building installations e.g. water and electricity;
- bathtub hoists that are covered by ISO 10535;
- 09 33 21 Bathtubs of ISO 9999:2011;
- stability and friction issues in relation to slippery surfaces due to soap;
- products that have been customised or custom-made for an individual user.