

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 168) "فريق عمل مواصفات الأطراف الصناعية وتقويم العظام" بتبني المواصفة الدولية رقم (ISO 8549-1:1989) "الأطراف الصناعية وتقويم العظام - المصطلحات - الجزء 1: مفردات عامة للأطراف الصناعية الخارجية والأجهزة التعويضية"، والتي أصدرتها "المنظمة الدولية للتقييس" وذلك بلغتها الأصلية. وقد اعتمدت هذه المواصفة كمواصفة سعودية متبناة بالتعديل بلغتها الأصلية وذلك في اجتماع مجلس الإدارة رقم (..) والذي عقد بتاريخ (../..../.. هـ الموافق ../..../.. م).

- التعديلات مشار إليها في ملحق التعديلات.

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 168) "Prosthetics and orthotics" has adopted the International Standard No. (ISO 8549-1:1989) "Prosthetics and orthotics -- Vocabulary -- Part 1: General terms for external limb prostheses and external orthoses" issued by "International Organization for Standardization" in its original language. This standard is adopted with modification 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 International Standard establishes a vocabulary, in English and French, of terms used in the field of external limb prosthetics and external orthotics.

This part of [ISO 8549](#) defines general terms used to describe these prostheses and orthoses, the anatomy of those parts of the human body most commonly fitted with these prostheses and orthoses, and the personnel and procedures involved in the practice of prosthetics and orthotics.

It does not apply to breast or other external prostheses used to replace other parts of the human body, to dental prostheses or orthoses, nor to internal prostheses and orthoses. Nor does it apply to orthoses that only encompass limb segments (i.e. orthoses used in fracture treatment and sports medicine).

NOTES

1 For the purposes of this International Standard, the abbreviated term 'prosthetics' and its derivatives only apply to external limb prosthetics; the abbreviated term 'orthotics' and its derivatives only apply to external orthotics.

2 Terms printed in italics are defined elsewhere in this part of [ISO 8549](#). Alphabetical indexes of terms in English and French are provided.

3 This International Standard does not include terms for orthoses used in fracture treatment; these terms may be considered at a future revision.

مرفق التعديلات

Project: SFDA.MD.168.DS.ISO 8549-1:1989

#	رقم الصفحة Page No.	رقم البند/البند الفرعي Clause/Subclause No.	رقم السطر Line No.	فقرة/ صورة/ جدول Paragraph/ Figure/ Table/	نوع الملاحظة Comment type	الملاحظات Comments	التعديل Modification
1				Title	ge	Delete the word "external" next to orthoses from the title	Change the title to be "Part 1: General terms for external limb prostheses and orthoses"
2	3	2.3.1			ge	2.3.1 orthotist: Person who, having completed an approved course of education and training, is authorized by an appropriate national authority to design, measure and fit <i>orthoses</i> .	change the definition of 2.3.1 to be: "orthotist: Person who, having completed an approved course of education and training, is authorized by an appropriate national authority to <u>assess</u> , design, measure and fit patient <u>with</u> <i>orthoses</i> ."

3	3	2.3.2				<p>2.3.2 prosthetist: Person who, having completed an approved course of education and training, is authorized by an appropriate national authority to design, measure and fit <i>prostheses</i>.</p>	<p>change the definition of 2.3.2 to be: “prothetist: Person who, having completed an approved course of education and training, is authorized by an appropriate national authority to <u>assess, design, measure and fit patient with</u> <i>prostheses</i>.”</p>
4	3	2.3.3				<p>2.3.3 orthotist/prosthetist : Person who, having completed an approved course of education and training, is authorized by an appropriate national authority to design, measure and fit <i>orthoses</i> and <i>prostheses</i>.</p>	<p>change the definition of 2.3.3 to be: orthotist/prosthetist : Person who, having completed an approved course of education and training, is authorized by an appropriate national authority to <u>assess, design, measure and fit patient with</u> <i>orthoses</i> and <i>prostheses</i>.</p>

5	4	2.3.7			ge	2.3.7 prosthetic (orthotic) casting and measurement Acquisition and recording of all information required to construct the prosthesis (orthosis) by means that may include the preparation of diagrams, tracings, measurements and negative casts of the body segments.	change the definition of 2.3.7 to be: “prosthetic (orthotic) casting and measurement Acquisition and recording of all information required to construct the prosthesis (orthosis) by means that may include the preparation of diagrams, tracings, measurements and by <u>negative casts or scanning</u> of the body segments.”
6	4				te		After 2.3.9, add a new sub-clause “2.3.10 scan modificatio: Process of modifying the scanned model obtained by 3D scanning camera through special software enabling the user to adjust shape, volume and borders, which specifies the whole, or part, of the form of the final prostheses or orthoses”
7	4				ed	2.3.10	Change the numbering to be 2.3.11
8	4				ed	2.3.11	Change the numbering to be 2.3.12

9	4				ed	2.3.12	Change the numbering to be 2.3.13
10	4				te		After 2.3.13, add a new sub-clause: "2.3.15 components programming : setting proper and customized software based on the patient to provide the designed function of smart (Microprocessor or Myo) Prostheses/Orthoses."
11	4				ed	2.3.13	Change the numbering to be 2.3.14
12	4				ed	2.3.14	Change the numbering to be 2.3.16
13	4	2.3.15			te	(including fit, function and appearance)	(including fit, function, <u>education</u> and appearance)
14	4				ed	2.3.15	Change the numbering to be 2.3.17
15	4				te		After 2.3.15, add a new sub-clause "2.3.18 Follow up and Adjustment: durability of function and safety of user, following the growth and body change."

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