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 المواصـــفة الدولية رقم (ISO 8549-3:1989) "الأطراف الصناعية وتقويم العظام - المصطلحات - الجزء ٣: مفردات متعلقة بالأجهزة التعويضية "، 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 ( ../../..... هـ) الموافق (../../.... 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 168) "Prosthetics and orthotics" has adopted the International Standard No. (ISO 8549-3:1989) "Prosthetics and orthotics -- Vocabulary -- Part 3: Terms relating to external orthoses" 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

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 <u>ISO 8549</u> defines terms relating to external orthoses that encompass joints.

It does not include terms for orthoses which only encompass limb segments as these orthoses are limited mainly to use in the treatment of fractures and in sports medicine. (These terms may be considered for inclusion at a future revision.)

## **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 in <u>ISO 8549-1</u>. Alphabetical indexes of terms in English and French are provided.
- 3 Users of this International Standard are also advised of the WHO International Classification of Impairments, Disabilities and Handicaps, published by the World Health Organization, Geneva, 1980.