## INTERNATIONAL STANDARD

ISO 13405-1

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# Prosthetics and orthotics — Classification and description of prosthetic components —

Part 1:

Classification of prosthetic components

Prothèses et orthèses — Classification et description des composants de prothèses —

Partie 1: Classification des composants de prothèses



#### **Foreword**

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 13405-1 was prepared by Technical Committee ISO/TC 168, *Prosthetics and orthotics*.

ISO 13405 consists of the following parts, under the general title Prosthetics and orthotics — Classification and description of prosthetic components:

- Part 1: Classification of prosthetic components
- Part 2: Description of lower-limb prosthetic components
- Part 3: Description of upper-limb prosthetic components

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#### Introduction

At present no internationally accepted method exists to classify or describe the components opposities. This situation causes considerable difficulty for manufacturers who are producing literature describing their products and for practitioners who are reporting on the prescriptions they employ in the treatment of particular patients.

The system proposed is designed to permit users to classify and describe systematically each component which is incorporated in a finished prosthesis, in a manner which clearly explains its principal characteristics. aring pro.

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Manufacturers' tradenames and details of the materials and manufacturing processes employed have been avoided.

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### Prosthetics and orthotics — Classification and description of prosthetic components —

#### Part 1: Classification of prosthetic components

#### 1 Scope

This part of ISO 13405 establishes a means of classifying the components of limb prostheses and their construction.

#### 2 Normative references

The following standards contain provisions, which, through reference in this text, constitute provisions of this part of ISO 13405. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 13405 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8549-1:1989, Prosthetics and orthotics - Vocabulary - Part 1: General terms.

ISO 8549-2: 1989, Prosthetics and orthotics — Vocabulary — Part 2: Terms relating to external limb prostheses and wearers of these prostheses.

#### 3 Definitions

For the purposes of this part of ISO 13405, the definitions given in ISO 8549-1 and ISO 8549-2 and the following definitions apply.

- **3.1 support:** That attribute of interface components which relates to the transmission of longitudinal (proximally directed) forces from the prosthesis to the body.
- **3.2 stabilization**: That attribute of interface components which relates to the transmission of transversely directed forces between the prosthesis and the body, and is concerned with the maintenance of the angular relationship of the prosthesis with the body consistent with use.
- **3.3 suspension**: That attribute of interface components concerned with the retention of the prosthesis on the body, i.e. the transmission of longitudinal (distally directed) forces from the prosthesis to the body.

#### 4 Classification

#### 4.1 General

Limb prostheses are integrated constructions comprising the following classes of components:

- a) interface components;
- b) functional components;
- c) alignment components;
- d) structural components;
- e) cosmetic components.

NOTE — Some components may belong to more than one class, e.g. alignment components may also serve as structural components.

Where a component property or characteristic is described as adjustable, this refers to the possibility of adjustment before use by the manufacturer, prosthetist or user.

Where a component property or characteristic is described as variable, this refers to intended changes occurring whilst in use.

#### 4.2 Interface components

Interface components of prostheses are in direct contact with the wearer. They are the means of achieving support, stabilization and suspension (see clause 3).

Interface components include:

- a) the socket;
- suspensory components, which maintain the prosthesis relative to the body.

NOTE — Interface components may contain elements which contribute to the activation and/or control of functional components.

#### 4.3 Functional components

Functional components of prostheses substitute for some of the dynamic and sensory attributes of the normal limb.

Functional components include:

- a) ankle-footdevices;
- b) terminal devices;
- c) joints.

#### 4.4 Alignment components

Alignment components of prostheses permit changes in the position of the components of a prosthesis relative to one another.