# INTERNATIONAL STANDARD

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

Part 1: Classification of prosthetic components

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## 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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see <a href="https://www.iso.org/directives">www.iso.org/directives</a>).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see <a href="https://www.iso.org/patents">www.iso.org/patents</a>).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword - Supplementary Information.

The committee responsible for this document is ISO/TC 168, Prosthetics and orthotics.

This second edition cancels and replaces the first edition (ISO 13405-1:1996), which has been technically revised with the following changes: lards.iteh.ai/catalog/standards/sist/de36e225-27f9-448e-8fcd-

a) liner added to the list of interface components;

b) functional components divided into lower and upper limb and listed.

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

### Introduction

This part of ISO 13405 was the first internationally accepted standard method of classifying the components of prostheses. It is designed to permit the users to classify systematically each component which is incorporated in a finished prosthesis. This part of 13405 is envisaged as being suitable for use by both manufacturers producing literature describing their products and practitioners who are reporting on the components used in the treatment of persons requiring prosthesis.

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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 specifies a means of classifying the components of limb prostheses and their construction.

#### 2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

#### 2.1

#### axial stabilization

attribute of interface components which relates to the transmission of longitudinal (proximally directed) forces from the prosthesis to the body

#### 2.2

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#### transverse stabilization

attribute of interface components which gelates to the transmission of transversely directed forces between the prosthesis and the body/catalog/standards/sist/de36e225-27f9-448e-8fcd-

99358f17eff2/iso-13405-1-2015 Note 1 to entry: Three forms of stabilization are required: anteroposterior, mediolateral, and rotational.

#### 2.3

#### suspension

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

#### 2.4

#### adjustable component

prosthetic component whose features can be changed before use by the manufacturer, prosthetist, or user

#### 2.5

#### adaptable component

prosthetic component whose features can be changed by the user to make it suitable for different situations

#### 2.6

#### auto-adaptive component

prosthetic component whose features change automatically in response to varying situations

#### 2.7

#### liner

removable lining worn between the stump and the inner surface of the socket

Note 1 to entry: It is used to modify the distribution of the forces associated with axial and transverse stabilization and it can additionally form a part of the prosthetic suspensory system.

#### **3** Classification

#### 3.1 General

Prostheses are externally applied devices used to replace wholly, or in part, an absent or deficient limb segment. They are integrated constructions comprising the following classes of components:

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

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

#### 3.2 Interface components

Interface components of a prosthesis are in direct contact with the wearer. They are the means of achieving axial stabilization, transverse stabilization, and suspension (see <u>Clause 3</u>). Interface components include:

a) the socket;

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- b) suspensory components, which maintain the prosthesis relative to the body;
- c) the liner.

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https://standards.iteh.ai/catalog/standards/sist/de36e225-27f9-448e-8fcd-NOTE Interface components can contain\_elements\_which4contribute to the activation and/or control of functional components.

#### **3.3 Functional components**

**3.3.1** Functional components of a prosthesis substitute for some of the dynamic and sensory attributes of the normal limb.

**3.3.2** Lower limb prosthetic functional components include:

- a) ankle-foot units;
- b) knee units;
- c) hip units;
- d) torque reducers;
- e) load attenuators (shock absorbers);
- f) turntables;
- g) external (side) joints.

**3.3.3** Upper limb prosthetic functional components include:

- a) terminal devices and digits;
- b) wrist units;

- c) elbow units;
- d) shoulder units;
- e) turntables;
- f) external (side) joints.

#### 3.4 Alignment components

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

#### 3.5 Structural components (prosthetic construction)

The structural components of prosthesis connect the interface, functional, and alignment components, and maintain the integrity of the prosthesis. Types of prosthetic construction include:

- a) endoskeletal: in which the structural components are internal and can be covered by finishing the components,
- b) exoskeletal: in which the structural components are external and also constitute the shape of the prosthesis.

#### 3.6 Finishing (cosmetic) components

Finishing components of prosthesis can simulate the appearance, and/or texture, and/or consistency of a normal limb. They include: (standards.iteh.ai)

- a) cosmetic fillers and shells, which provide the desired shape of the prosthesis and can simulate the consistency of soft tissue; ISO 13405-1:2015
- b) prosthetic skins, stockings, and gloves, which compose the outermost layer of the prosthesis and can simulate the colour, and/or texture of the human skin.