

## ประกาศกระทรวงอุตสาหกรรม

ฉบับที่ ๓๕๖๓ (พ.ศ. ๒๕๕๑)

ออกตามความในพระราชบัญญัติมาตรฐานผลิตภัณฑ์อุตสาหกรรม

พ.ศ. ๒๕๑๑

เรื่อง กำหนดมาตรฐานผลิตภัณฑ์อุตสาหกรรม

กายอุปกรณ์เทียมและกายอุปกรณ์เสริม - การแบ่งประเภทและการเรียกชื่อ

กายอุปกรณ์เสริมที่ใช้ภายนอกและชิ้นส่วนของกายอุปกรณ์เสริม

อาศัยอำนาจตามความในมาตรา ๑๕ แห่งพระราชบัญญัติมาตรฐานผลิตภัณฑ์อุตสาหกรรม พ.ศ. ๒๕๑๑ รัฐมนตรีว่าการกระทรวงอุตสาหกรรมออกประกาศกำหนดมาตรฐานผลิตภัณฑ์อุตสาหกรรมกายอุปกรณ์เทียมและกายอุปกรณ์เสริม - การแบ่งประเภทและการเรียกชื่อกายอุปกรณ์เสริมที่ใช้ภายนอกและชิ้นส่วนของกายอุปกรณ์เสริม มาตรฐานเลขที่ มอก. 2402-2551 ไว้ ดังมีรายการละเอียดต่อท้ายประกาศนี้

ประกาศ ณ วันที่ ๑๒ ธันวาคม พ.ศ. ๒๕๕๑

พลตำรวจเอก ประชา พรหมนอก

รัฐมนตรีว่าการกระทรวงอุตสาหกรรม

**มาตรฐานผลิตภัณฑ์อุตสาหกรรม  
กายอุปกรณ์เทียมและกายอุปกรณ์เสริม –  
การแบ่งประเภทและการเรียกชื่อ  
กายอุปกรณ์เสริมที่ใช้ภายนอก  
และชิ้นส่วนของกายอุปกรณ์เสริม**

**บทนำ**

มาตรฐานผลิตภัณฑ์อุตสาหกรรมนี้ กำหนดขึ้นโดยรับ ISO 13404 : 2007 Prosthetics and orthotics- Categorization and description of external orthoses and orthotic components มาใช้ในระดับเหมือนกันทุกประการ (identical) โดยใช้ ISO ฉบับภาษาอังกฤษเป็นหลัก

**ขอบข่าย**

มาตรฐานผลิตภัณฑ์อุตสาหกรรมนี้กำหนดการแบ่งประเภทและการเรียกชื่อกายอุปกรณ์เสริมที่ใช้ภายนอกตามชิ้นส่วนของอุปกรณ์เสริมนั้นทำหน้าที่ควบคุม

**เอกสารอ้างอิง**

รายละเอียดให้เป็นไปตาม ISO 13404 : 2007 ข้อ 2

**บทนิยาม**

ความหมายของคำที่ใช้ในมาตรฐานผลิตภัณฑ์อุตสาหกรรมนี้ ให้เป็นไปตาม ISO 13404 : 2007 ข้อ 3

**การแบ่งประเภทของกายอุปกรณ์เสริมตามหน้าที่**

รายละเอียดให้เป็นไปตาม ISO 13404 : 2007 ข้อ 4

**การแบ่งประเภทของชิ้นส่วนในแต่ละกายอุปกรณ์เสริม**

รายละเอียดให้เป็นไปตาม ISO 13404 : 2007 ข้อ 5

## **Introduction**

No internationally accepted method has been available to classify or describe external orthoses and the components from which they are assembled. This situation has created difficulty for practitioners prescribing orthoses, for manufacturers producing literature describing their products, and for those reporting on prescriptions employed in the treatment of particular patient groups.

This International Standard permits the systematic classification and description of both the finished orthosis and the components from which it is assembled in a manner that clearly explains their principal characteristics.

Manufacturers' trade names and details of materials and manufacturing processes have been avoided.

# Prosthetics and orthotics — Categorization and description of external orthoses and orthotic components

## 1 Scope

ISO 13404 establishes a means of classifying and describing external orthoses and the components from which they are assembled.

## 2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8549-1, *Prosthetics and orthotics — Vocabulary — Part 1: General terms for external limb prostheses and external orthoses*

ISO 8549-3, *Prosthetics and orthotics — Vocabulary — Part 3: Terms relating to external orthoses*

ISO 8551, *Prosthetics and orthotics — Functional deficiencies — Description of the person to be treated with an orthosis, clinical objectives of treatment, and functional requirements of the orthosis*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8549-1, ISO 8549-3 and ISO 8551 and the following apply.

### 3.1

#### **custom fabricated orthosis**

device that is designed and manufactured to meet the functional requirements of the individual user based on information such as moulds, models, measurements and images

### 3.2

#### **prefabricated orthosis**

device that has been designed to meet particular functional requirements and is normally available in a range

NOTE The selected orthosis might require adjustment for the individual user.

## 4 Classification of orthoses

### 4.1 General description

Describe the orthosis by reference to the body segments and joints which it encompasses using the terminology defined in ISO 8549-3 and shown in Table 1.

**Table 1 — Terminology defined in ISO 8549-3**

Device	Abbreviation
Foot orthosis	FO
Ankle-foot orthosis	AFO
Knee orthosis	KO
Knee-ankle-foot orthosis	KAFO
Hip orthosis	HpO
Hip-knee orthosis	HKO
Hip-knee-ankle-foot orthosis	HKAFO
Finger orthosis	FO
Hand orthosis	HdO
Wrist-hand orthosis	WHO
Wrist-hand-finger orthosis	WHFO
Elbow orthosis	EO
Elbow-wrist-hand orthosis	EWHO
Shoulder orthosis	SO
Shoulder-elbow orthosis	SEO
Shoulder-elbow-wrist-hand orthosis	SEWHO
Sacro-iliac orthosis	SIO
Lumbo-sacral orthosis	LSO
Thoraco-lumbo-sacral orthosis	TLSO
Cervical orthosis	CO
Cervico-thoracic orthosis	CTO
Cervico-thoraco-lumbo-sacral orthosis	CTLSO

## 4.2 Function

**4.2.1** The function of the orthosis may be to manage a deformity:

- a) to prevent a deformity (i.e. to stop a joint or segment moving into an abnormal alignment);
- b) to reduce a deformity (i.e. to move a joint or segment to an improved alignment and hold the correction obtained);
- c) to hold a deformity (i.e. to prevent an irreducible deformity from increasing).

Specify the joint(s) and/or segment(s) and the alignment which the orthosis is designed to achieve.

**4.2.2** The function of the orthosis may be to change the range of motion of a joint(s):

- a) to limit the range of motion of a joint;
- b) to increase the range of motion of a joint.

Specify the joint(s) and the range(s) of motion which the orthosis is designed to achieve.

**4.2.3** The function of the orthosis may be to change the dimensions of a limb segment(s):

- a) to add to the length of a segment;
- b) to improve the shape of a segment.

Specify the segment and the magnitude of the length addition and/or the change of shape that the orthosis provides.

**4.2.4** The function of the orthosis may be to manage abnormal neuromuscular function:

- a) to compensate for weak muscle activity;
- b) to control the effect of muscle hyperactivity.

Specify the joint moment(s) which the orthosis is designed to produce.

**4.2.5** The function of the orthosis may be to reduce or redistribute the load on tissue (e.g. to redistribute pressure on the plantar surface of the foot or to reduce the load on a tibial fracture).

Specify the tissue loading that the orthosis is designed to reduce or redistribute.

### **4.3 Type of fabrication**

The orthosis may be:

- a) **custom fabricated**

or

- b) **prefabricated.**

State the type of fabrication.

## **5 Classification of orthotic components**

### **5.1 General**

External orthoses are constructions comprising the following classes of components:

- a) interface components;
- b) articulating components;
- c) structural components;
- d) cosmetic components.

NOTE Some components might belong to more than one class, e.g. moulded plastic shells may serve as interface, articulating and structural components.

### **5.2 Interface components**

Interface components of orthoses are those in direct contact with the user. They transmit the forces between the orthosis and the user which result from its function and may retain the orthosis in place.

Interface components include the following.

- a) **Shells**, which encompass body segments (or parts thereof). They are wholly or partially circumferential and may be stiff or flexible and may be opened for entry. Open shells may be closed by straps. Shells apply forces perpendicular to the surface of the body.

A shell may be shaped to be weight bearing:

- 1) the proximal part of a shell is sometimes referred to as the **brim**;
  - 2) stiff narrow shells are sometimes referred to as **bands**;
  - 3) flexible narrow shells are sometimes referred to as **cuffs**.
- b) **Pads**, which apply a localized force perpendicular to the surface of a body segment or at a joint and may require straps to achieve this effect.
- c) **Straps**, which apply a localized force mainly perpendicular to the surface of a body segment or at a joint.
- d) **Foot orthoses**, comprising insoles, inserts, pads, arch supports, heel cushions and heel cups which modify the distribution of the forces on the surface of the foot.
- e) **Shoes**, which even when not an integral part of orthoses may be essential for their function.

State the interface components utilized in the construction of the orthosis.

### 5.3 Articulating components

NOTE Articulating components of orthoses allow or control the motions of anatomical joints.

#### 5.3.1 General

Describe the articulating components by including the information given in 5.3.2 to 5.3.6.

#### 5.3.2 Types of articulating component

The types of articulating component are identified by reference to the anatomical joints whose motions they are intended to allow or control. They include:

- a) joints for spinal orthoses;
- b) hip joints;
- c) knee joints;
- d) ankle joints;
- e) foot/toe joints;
- f) shoulder joints;
- g) elbow joints;
- h) wrist joints;
- i) hand/finger joints.

State the types of articulating component, i.e. the joints, in the orthosis.

### 5.3.3 Permissible motions

The permissible motions of the joints when assembled in the specific orthosis may be:

- a) flexion/extension;
- b) dorsiflexion/plantarflexion;
- c) dorsal/palmar flexion;
- d) abduction/adduction;
- e) internal/external rotation;
- f) supination/pronation;
- g) lateral flexion;
- h) lateral rotation.

State for each joint the permissible motions.

State if the action of the joint results in simultaneous motion in more than one of these planes.

### 5.3.4 Form of articulation

State for each permissible motion whether it is achieved by:

- a) movement between parts of the joint  
and/or
- b) deformation of a part of the joint.

### 5.3.5 Axis of rotation

Motion is either

- a) **monocentric**, in which the axis of rotation is constant for all angles of the joint  
or
- b) **polycentric**, in which the axis of rotation changes with the angle of the joint.

State for each permissible motion whether it is monocentric or polycentric.

### 5.3.6 Controls

Joints may incorporate features which control their motion during use.

These include mechanisms which:

- a) **lock** the joint at a specified angle
  - activation of locking/unlocking may be **manual** or **automatic**, in the following combinations:
    - manual lock/manual unlock;



- automatic lock/manual unlock;
- automatic lock/automatic unlock;

- b) **limit** the range of motion of the joint;
- c) **assist** or **resist** movement of the joint.

State the type of control mechanism for each permissible motion of each joint.

State in the case of locks, the method of activation and the angle at which the joint is locked.

State in the case of limiting mechanisms, the limits of permitted motion.

State in the case of assist or resist mechanisms, the direction of the motion assisted or resisted.

State if any of these features is adjustable.

#### 5.4 Structural components

Structural components of orthoses connect the articulating and interface components and maintain the alignment of the orthosis.

They include:

- a) **uprights**
  - 1) Specify the location of any uprights by reference to
    - i) the anatomical segment(s) situated alongside;
    - ii) their relationship to the segment(s) as:
      - I) medial,
      - II) lateral,
      - III) anterior,
      - IV) posterior;
    - iii) and whether they are length adjustable;

NOTE Uprights situated alongside the leg might insert, at their distal end, in a tube mounted in the footwear as part of an articulating component.

- b) **shells** (including bands)

- 1) Specify the location of any shells by reference to the anatomical segments which they encompass.

NOTE The structural properties of shells might be enhanced by corrugations or by the use of inserts.

### 5.5 Cosmetic components

Cosmetic components are the means of providing shape, colour and texture to orthoses.

They include:

- a) **fillers** which compensate for soft tissue deficits;
- b) **covers** or **sleeves** which are applied over the structural and other components to improve appearance.

State the cosmetic component(s) used in the orthosis.