EESTI STANDARD EVS-EN ISO 22523:2006

Jäsemete välimised proteesid ja välimised ortopeediaseadmed. Nõuded ja katsemeetodid

External limb prostheses and external orthoses - Requirements and test methods

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 22523:2006 sisaldab Euroopa standardi EN ISO 22523:2006 ingliskeelset teksti. Käesolev dokument on jõustatud 24.11.2006 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 22523:2006 consists of the English text of the European standard EN ISO 22523:2006. This document is endorsed on 24.11.2006 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This International Standard specifies requirements and test methods for external limb prostheses and external orthoses, including the following classifications from ISO 9999:06 03 - 06 15 Orthoses 06 18 - 06 27 Limb prostheses It covers strength, materials, restrictions on use, risk and the provision of information associated with the normal conditions of use of both components and assemblies of components.	**Scope:** This International Standard specifies requirements and test methods for external limb prostheses and external orthoses, including the following classifications from ISO 9999:06 03 - 06 15 Orthoses 06 18 - 06 27 Limb prostheses It covers strength, materials, restrictions on use, risk and the provision of information associated with the normal conditions of use of both components and assemblies of components.

ICS 11.040.40

Võtmesõnad: contamination, definitions, design, ergonomics, flammability, information, materials, mechanical strength, medical equipment, operating requirements, orthotics, prosthetic devices, safety, specifications, surgical implants, tests, toxicity

EUROPEAN STANDARD

NORME EUROPÉENNE

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EN ISO 22523

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English Version

External limb prostheses and external orthoses - Requirements and test methods (ISO 22523:2006)

Prothèses de membre externes et orthèses externes - Exigences et méthodes d'essai (ISO 22523:2006)

Externe Gliedmaßenprothesen und externe Orthesen - Anforderungen und Prüfverfahren (ISO 22523:2006)

This European Standard was approved by CEN on 13 April 2006.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

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Foreword

This document (EN ISO 22523:2006) has been prepared by Technical Committee ISO/TC 168 "Prosthetics and orthotics" in collaboration with Technical Committee CEN/TC 293 "Assistive products for persons with disability", the secretariat of which is held by SIS.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2007, and conflicting national standards shall be withdrawn at the latest by April 2007.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 22523:2006 has been approved by CEN as EN ISO 22523:2006 without any modifications.

ANNEX ZA
(informative)

Clauses of this European Standard addressing essential requirements or other provisions of EU Directives.

This European Standard has been prepared under a mandate given to the European Community and the European Free Trade Association and supports corresponding essential requirements of EU Directive 93/42/EEC concerning medical devices and EU Directive 99/5/EC on radio equipment and telecommunications terminal equipment.

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

The clauses of this standard are likely to support requirements of Directive 93/42 EEC concerning medical devices (see Table ZA.1) and of Directive 99/5/EC on radio equipment and telecommunications terminal equipment (see Table ZA.2).

Compliance with this standard provides one means of conforming with the corresponding essential requirements of the Directive concerned and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and EU Directive 93/42/EEC

Clauses/sub-clauses of this European Standard	Corresponding annexes/paragraphs of Directive 93/42/EEC concerning medical devices — Annex I: Essential requirements	Comments
All	1	
All and specifically: 4.1, 5.1, 5.4, 7, 8.2, 8.3, 9, 11.1, 11.2	2	Specifically: risk management, flammability/toxicity, corrosion/degradation, EMC, battery-powered devices, surface temperature, moving parts, connections
All and specifically 4.2	3	Specifically: intended performance
All and specifically 4.2, 4.4	4	Specifically: intended performance, strength
All and specifically 13, 14	5	Specifically: information, packaging
All and specifically 4.1	6	Specifically: risk management
5.1, 5.2	7.1	Flammability/toxicity, biocompatibility/contaminants/residues
5.2, 13, 14	7.2	Biocompatibility/contaminants/residues, information, packaging
5.2.2, 5.4	7.3	Contaminants/residues, corrosion/degradation
5.2, 5.4, 11.2	7.6	Biocompatibility/contaminants/residues, corrosion/ degradation, connections
5.2, 5.3	8.1	Biocompatibility/contaminants/residues, infection and microbiological contamination
14	8.6	Packaging

Table ZA.1 (*continued*)

Clauses/sub-clauses of this European Standard	Corresponding annexes/paragraphs of Directive 93/42/EEC concerning medical devices — Annex I: Essential requirements	Comments
12.1, 13	9.1	Restrictions on use, information
7, 9, 11.1, 12.2,12.3	9.2	EMC, surface temperature, moving parts, forces on soft tissues on the human body, ergonomic principles
5.1, 8.2 , 8.4	9.3	Inflammability/toxicity, battery powered devices
8.6	11.3.1	Protection against unintended radiation
8.3	12.1	Electronic programmable systems
8.1, 8.2	12.2	Battery-powered devices
7	12.5	EMC
8	12.6	Electrical safety
11, 12	12.7.1	Design and mechanical requirements
6	12.7.2	Vibration
6	12.7.3	Noise
8.2, 11.2	12.7.4	Battery-powered devices, connections
9	12.7.5	Surface temperature
8.5	12.8.2	Skin contact electrodes stimulate by means of electrical energy and may be considered as energy supply in the sense of ER 12.8
13.1, 13.2	12.9	Information
13	13	Information, packaging
10	13.6. l)	Information on sterilization if specific devices require to be sterilized for particular applications
4.3	14	Clinical evaluation

Table ZA.2 — Correspondence between this European Standard and EU Directive 99/5/EC

Clauses/sub-clauses of this European Standard	Corresponding annexes/paragraphs of Directive 99/5/EC concerning radio equipment and telecommunications terminal equipment	Comments
8.1, 8.2, 8.3, 8.4, 8.7.1	Article 3.1 (a)	
7, 8.7.1	Article 3.1 (b)	
8.7.2	Article 3.2	
8.7.3	Article 3.3 (f)	

INTERNATIONAL STANDARD

ISO 22523

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External limb prostheses and external orthoses — Requirements and test methods

Prothèses de membre externes et orthèses externes — Exigences et méthodes d'essai

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

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.

ISO 22523 was prepared by Technical Committee ISO/TC 168, *Prosthetics and orthotics.*

Introduction

This International Standard has been prepared in close collaboration with Technical Committee CEN/TC 293 *Technical aids for disabled persons*.

This International Standard represents the revised version of the Harmonized European Standard EN 12523:1999 already implemented by the member countries of the European Union and the European Free Trade Association in accordance with the CEN/CENELEC Internal Regulations. Consequently, these regulations apply accordingly.

This International Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this International Standard.

This International Standard provides one means to demonstrate that external limb prostheses and external orthoses, which are also medical devices, conform to the essential requirements outlined in general terms in Annex 1 of the EU Directive 93/42/EEC on medical devices.

This International Standard also provides means to demonstrate that external limb prostheses and external orthoses with radio equipment according to definition 3.8 conform to the essential requirements of the EU Directive 99/5/EC on radio equipment and telecommunications terminal equipment.

This standard is not intended to provide a means of showing conformity with the requirements of any other directive.

There are three levels of European Standard dealing with technical aids for disabled persons. These are as follows, with level 1 being the highest:

Level 1: General requirements for technical aids

Level 2: Particular requirements for families of technical aids

Level 3: Specific requirements for types of technical aids.

Where standards for particular aids or groups of aids exist (level 2 or 3), the requirements of lower-level standards take precedence over higher-level standards. Therefore, to address all requirements for a particular aid, it is necessary to consult first, standards of the lowest available level.

This is a combined level 2- and 3-standard (lowest possible) for external limb prostheses and external orthoses, as specified in the scope.

In this International Standard, in addition to the reference to existing test standards, test methods for several types of prostheses and orthoses are specified in separate annexes A to D.

Annex ZA is included to show the parts of this European Standard which address the essential requirements of EU Directives 93/42/EEC and 99/5/EC.

NOTE Although this International Standard does not contain references to the level 1-standard EN 12182 *Technical aids for disabled persons — General requirements and test methods*, it is recommended that EN 12182 be consulted.

External limb prostheses and external orthoses — Requirements and test methods

1 Scope

This International Standard specifies requirements and test methods for external limb prostheses and external orthoses, including the following classifications from ISO 9999:

06 03 - 06 15 Orthoses

06 18 - 06 27 Limb prostheses

It covers strength, materials, restrictions on use, risk and the provision of information associated with the normal conditions of use of both components and assemblies of components.

This International Standard does not cover special seating as it is not classified as an orthosis in ISO 9999 and it is not normally body worn.

NOTE 1 It is intended to cover orthopaedic footwear (classification 06 33) in the future.

NOTE 2 The application of Quality Systems as described or referred to in ISO 13485 and ISO 13488 may be appropriate.

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 8548-1, *Prosthetics and orthotics — Limb deficiencies — Part 1: Method of describing limb deficiencies present at birth*

ISO 8548-2, *Prosthetics and orthotics — Limb deficiencies — Part 2: Method of describing lower limb amputation stumps*

ISO 8548-3, *Prosthetics and orthotics — Limb deficiencies — Part 3: Method of describing upper-limb amputation stumps*

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

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

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

ISO 10328, *Prosthetics — Structural testing of lower-limb prostheses — Requirements and test methods*

ISO 13404:2005, *Prosthetics and orthotics — Classification and description of external orthoses and orthotic components*

ISO 13405-1, *Prosthetics and orthotics — Classification and description of prosthetic components — Part 1: Classification of prosthetic components*

ISO 13405-2, *Prosthetics and orthotics — Classification and description of prosthetic components — Part 2: Description of lower-limb prosthetic components*

ISO 13405-3, *Prosthetics and orthotics — Classification and description of prosthetic components — Part 3: Description of upper-limb prosthetic components*

ISO 15032, *Prosthetics — Structural testing of hip units*

ISO 22675, *Prosthetics — Testing of ankle-foot devices and foot units — Requirements and test methods*

IEC 60335-2-17 *Household and similar electrical appliances — Safety — Part 2-17: Particular requirements for blankets, pads and similar flexible heating appliances*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*

IEC 60601-1-2, *Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests*

IEC 61000-4-3, *Electromagnetic compatibility (EMC) — Part 4-3: Testing and measurement techniques — Radiated, radio-frequency, electromagnetic field immunity test*

EN 1041, *Information supplied by the manufacturer with medical devices*

EN 50082-2, *Electromagnetic compatibility (EMC) — Generic immunity — Part 2: Industrial environment*

3 Terms and definitions

For the purposes of this document, the definitions of ISO 8548 Parts 1 to 3, ISO 8549 Parts 1 to 3 (except the definitions for the terms “(external limb) prosthetic device” and “(external) orthotic device”, ISO 13404 (except the definitions for the terms “side member” and 'joint assembly') and ISO 13405 Parts 1 to 3 together with the following terms and definitions apply. The definitions are listed in the order of citation.

3.1
(external limb) prosthetic device
external limb prosthesis
externally applied device consisting of a single component or an assembly of components used to replace wholly, or in part, an absent or deficient lower or upper-limb segment

NOTE In this International Standard the term “prosthetic device” is used.

3.2
(external) orthotic device
external orthosis
externally applied device consisting of a single component or an assembly of components applied to the whole or part of the lower limb, upper-limb, trunk, head or neck and their intermediate joints to assist the neuro-muscular and skeletal systems

NOTE In this International Standard the term “orthotic device” is used.

3.3
user
person using (wearing) the prosthetic or orthotic device

