# Jäsemete välimised proteesid ja välimised ortopeediaseadmed. Nõuded ja katsemeetodid

External limb prostheses and external orthoses - Requirements and test methods

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

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| Käesolev Eesti standard EVS-EN 12523:1999 sisaldab Euroopa standardi EN 12523:1999 ingliskeelset teksti.<br><br>Käesolev dokument on jõustatud 23.11.1999 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.<br><br>Standard on kättesaadav Eesti standardiorganisatsioonist. | This Estonian standard EVS-EN 12523:1999 consists of the English text of the European standard EN 12523:1999.<br><br>This document is endorsed on 23.11.1999 with the notification being published in the official publication of the Estonian national standardisation organisation.<br><br>The standard is available from Estonian standardisation organisation. |

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| **Käsitlusala:**<br>This standard specifies requirements and test methods for external limb prostheses and external orthoses. | **Scope:**<br>This standard specifies requirements and test methods for external limb prostheses and external orthoses. |

**ICS** 11.180

**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
# EUROPÄISCHE NORM

EN 12523

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**English version**

## External limb prostheses and external orthoses

Requirements and test methods

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

Externe Gliedmaßenprothesen und externe Orthesen – Anforderungen und Prüfverfahren

This European Standard was approved by CEN on 1998-11-08.

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.

The European Standards exist 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.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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## Foreword

This European Standard has been prepared by Technical Committee CEN/TC 293 "Technical aids for disabled persons", 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 July 1999, and conflicting national standards shall be withdrawn at the latest by July 1999.

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

This European 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 Z, which is an integral part of this standard.

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

There are three levels of European Standards 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 start with 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 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-D.

Annex Z (informative) is included to show the parts of this European Standard which address the essential requirements of EU Directive 93/43/EEC.

**Note 1**: The test methods specified in Annexes A and C require further work on evaluation of practicality and/or amendment/completion and/or verification/validation to establish the basis from which to decide on a change of their status. In order to allow their use as guidance, for the purposes of this edition of EN 12523, they are included as informative parts.

The test methods specified in Annex D have primarily been developed and applied to establish a data base from which to decide on the applicability of ranges of operating force specified in EN 614-1 and/or other standards referred to therein such as EN 894-3. As these test methods are considered to be also suitable for the purposes of this standard, Annex D is included as informative part.

**Note 2:** At the time of publication of this combined level 2- and 3-standard, the level 1-standard prEN 12182 "Technical aids for disabled persons - general requirements and test methods" has still been in the final draft stage prior to formal vote. In consideration of the possibility of unknown changes in prEN 12182:1998 after formal vote and before publication, this edition of EN 12523 does not contain references to it. Specific clauses of prEN 12182:1997 originally referred to as being applicable have been adopted as regular parts of the main body of this standard. It is, however, recommended to pay attention to EN 12182 once it is published.

## 1 Scope

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

06 03 - 06 15Orthoses
06 18 - 06 27Limb 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 European Standard does not cover special seating as it is not classified as an orthosis in EN ISO 9999 and it is not normally body worn.

**NOTE 1:** It is intended to cover orthopaedic foot-wear (classification 06 33) in the future.

**NOTE 2:** The application of Quality Systems as described or referred to in EN 46001 and EN 46002 may be appropriate.

## 2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

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| EN 1041 | Information supplied by the manufacturer with medical devices |
| EN ISO 9999:1998 | Technical aids for disabled persons - Classification (ISO 9999:1998) |
| EN ISO 10993-1 | Biological evaluation of medical devices - Part 1: Evaluation and testing (ISO 10993-1:1997) |
| EN 50082-2 | Electromagnetic compatibility (EMC) - Generic immunitiy - Part 2: Industrial environment |
| EN 60601-1:1987 | Safety of medical electrical equipment - Part 1: General requirements |
| EN 60601-1-2 | Medical electrical equipment - Part 1: General requirements for safety - 2. Collateral standard: Electromagnetic compatibility - Requirements and test methods |
| 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 |

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| 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 10328-1 | Prosthetics - Structural testing of lower-limb prostheses - Part 1: Test configurations |
| ISO 10328-2 | Prosthetics - Structural testing of lower-limb prostheses - Part 2: Test samples |
| ISO 10328-3 | Prosthetics - Structural testing of lower-limb prostheses - Part 3: Principal structural tests |
| ISO 10328-4 | Prosthetics - Structural testing of lower-limb prostheses - Part 4: Loading parameters of principal structural tests |
| ISO 10328-5 | Prosthetics - Structural testing of lower-limb prostheses - Part 5: Supplementary structural tests |
| ISO 10328-6 | Prosthetics - Structural testing of lower-limb prostheses - Part 6: Loading parameters of supplementary structural tests |
| ISO 10328-7 | Prosthetics - Structural testing of lower-limb prostheses - Part 7: Test submission document |
| ISO 10328-8 | Prosthetics - Structural testing of lower-limb prostheses - Part 8: Test report |
| 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/DIS 15032 | Prosthetics - Structural testing of hip units |

## 3 Definitions

For the purposes of this standard the definitions of ISO 8548 Parts 1 to 3, ISO 8549 Parts 1 to 3 (except the definitions for the terms '(external limb) prosthic device' and '(external) orthotic device') and ISO 13405 Parts 1 to 3 together with the following definitions apply (definitions listed in the order of use/application).

**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.