SLOVENSKI STANDARD
SIST EN ISO 22675:2006

01-december-2006

Protetika - Preskušanje mehanizmov za gleženj in stopalo ter enot za stopalo - Zahteve in preskusne metode (ISO 22675:2006)

Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods (ISO 22675:2006)

Prothetik - Prüfung von Knöchel-Fuß-Passteilen und Fußeinheiten - Anforderungen und Prüfverfahren (ISO 22675:2006)

Protheses - Essais d'articulations cheville-pied et unités de pied - Exigences et méthodes d'essai (ISO 22675:2006)

Ta slovenski standard je istoveten z: **EN ISO 22675:2006**

ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics

SIST EN ISO 22675:2006 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 22675

October 2006

ICS 11.040.40

English Version

Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods (ISO 22675:2006)

Prothèses - Essais d'articulations cheville-pied et unités de pied - Exigences et méthodes d'essai (ISO 22675:2006)

Prothetik - Prüfung von Knöchel-Fuß-Passteilen und Fußeinheiten - Anforderungen und Prüfverfahren (ISO 22675:2006)

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.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

Ref. No. EN ISO 22675:2006: E

Foreword

This document (EN ISO 22675:2006) 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 22675:2006 has been approved by CEN as EN ISO 22675:2006 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 CEN by the European Commission and the European Free Trade Association and supports corresponding essential requirements of EU Directive 93/42/EEC concerning medical devices.

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

The following clauses of this standard are likely to support requirements of Directive 93/42/EEC concerning medical devices: 5, 6, 7, 8, 9, 10, 15, 16, 17, 20 and 21 (see Table ZA.1).

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

Table ZA.1 — Correspondence between this European Standard and EU Directives

Clauses of this European Standard	Corresponding Essential Requirements of Directive 93/42/EEC	Comments
5; 6; 7; 8; 9; 10; 15; 16; 17	2, 4, 12.7.1	
5; 20; 21	9.1	
5; 20; 21	13.1	Essential requirement 13.1 is not fully covered here; only the aspects of classification are addressed.
20	13.3 k)	

INTERNATIONAL STANDARD

ISO 22675

First edition
2006-10-01

Prosthetics — Testing of ankle-foot devices and foot units — Requirements and test methods

Prothèses — Essais d'articulations cheville-pied et unités de pied — 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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Contents

Page

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 22675 was prepared by Technical Committee ISO/TC 168, *Prosthetics and orthotics*.

Introduction

This International Standard offers alternatives to the structural tests on ankle-foot devices and foot units specified in 17.2 of ISO 10328:2006, which still suffer from several “weaknesses”, such as:

a) the inconsistency of the lines of application of the heel and forefoot test forces with those of the test forces of test loading conditions I and II for the principal structural tests specified in 16.2 (static tests) and 16.3 (cyclic test) of ISO 10328:2006;

b) the unrealistic course and magnitude of loading in the phase between the instants of maximum heel and forefoot loading during the cyclic test;

c) the effect of periodical “stepping in a hollow” during the cyclic test, resulting from simultaneous heel and forefoot loading at different angles.

In this relation it is important to note that the complexity of the test equipment required for the testing of ankle-foot devices and foot units specified in this International Standard is low, comparable to that of the test equipment required for the corresponding separate structural tests specified in ISO 10328. Apparently, basic components of both types of test equipment are similar and can be re-used in a modified design.

Finally, it has to be noted that the potential of the general concept applied to the test procedures specified in this International Standard allows other applications directed to the assessment of specific performance characteristics of ankle-foot devices and foot units that may be of relevance in the future.

In order to allow continuity of testing by checking the test methods for ankle-foot devices and foot units specified in this International Standard against those specified in 17.2 of ISO 10328:2006, a transition period will be established, during which both test methods are valid. For practical reasons, this transition period will be adapted to the period of time after which the systematic review of ISO 10328:2006 and this International Standard is indicated. The systematic review of both standards is expected to result, among other outcomes, in the finding on whether the test methods specified in this International Standard have demonstrated their suitability.

NOTE Further guidance on the specification of the test loading conditions and test loading levels and on the design of appropriate test equipment is given in a separate document, published as a Technical Report (see Bibliography).

Prosthetics — Testing of ankle-foot devices and foot units — Requirements and test methods

1 Scope

IMPORTANT — This International Standard is *suitable* for the assessment of the conformity of prosthetic ankle-foot devices and foot units with the strength requirements specified in 4.4 of ISO 22523:2006 (see NOTE 1). Prosthetic ankle-foot devices and foot units on the market, which have demonstrated their compliance with the strength requirements specified in 4.4 of EN 12523:1999 through submission to the relevant tests of ISO 10328:1996, need not be retested to this International Standard.

WARNING — This International Standard is *not suitable* to serve as a guide for the selection of a specific ankle-foot device or foot unit in the prescription of an individual lower limb prosthesis! Any disregard of this warning can result in a safety risk for amputees.

This International Standard primarily specifies a cyclic test procedure for ankle-foot devices and foot units of external lower limb prostheses, distinguished by the potential to realistically simulate those loading conditions of the complete stance phase of walking from heel strike to toe-off that are relevant to the verification of performance requirements such as strength, durability and service life.

This potential is of particular importance for the assessment of the performance of a variety of recent designs of ankle-foot devices and foot units with specific characteristics that will only develop under realistic conditions of loading.

In addition, this International Standard specifies a static test procedure for prosthetic ankle-foot devices and foot units, consisting of a static proof test and a static ultimate strength test, distinguished, besides other features, (see NOTE 2) by the potential to generate heel and forefoot forces at lines of action conforming to those occurring at the instants of maximum heel and forefoot loading during the cyclic test.

The loading conditions addressed in the third paragraph are characterized by a loading profile determined by the resultant vector of the vertical and horizontal (A-P) ground reaction forces and by a locomotion profile determined by the tibia angle.

The test loading conditions specified in this International Standard are characterized by standardized formats of these loading and locomotion profiles, to be uniformly applied by the cyclic and static test procedures to each sample of ankle-foot device or foot unit submitted for test.

According to the concept of the tests of this International Standard, each sample of ankle-foot device or foot unit submitted for test is, nevertheless, free to develop its individual performance under load.

NOTE 1 ISO 22523 (formerly EN 12523) addresses those of the Essential Requirements listed in Annex I of the European Medical Device Directive 93/42/EEC that are applicable to external limb prostheses and external orthoses.

NOTE 2 The lines of action of the heel and forefoot forces generated by the static test procedure specified in this International Standard approach those determining the sagittal plane loading of the test loading conditions I and II for the principal structural tests specified in ISO 10328, without changing the values of the angles of the heel and forefoot platform(s) for the structural tests on ankle-foot devices and foot units specified in ISO 10328.