SLOVENSKI STANDARD

SIST EN ISO 10328:2006

01-december-2006

Protetika - Preskuġanje strukture protez spodnjih okonį in - Zahteve in preskusne metode (ISO 10328:2006)

Prosthetics - Structural testing of lower-limb prostheses - Requirements and test methods (ISO 10328:2006)

Prothetik - Prüfung der Struktur von Prothesen der unteren Gliedmaßen - Anforderungen und Prüfverfahren (ISO 10328:2006)

Protheses - Essais portant sur la structure des protheses de membres inférieurs - Exigences et méthodes d'essai (ISO 10328:2006)

Ta slovenski standard je istoveten z: **EN ISO 10328:2006**

ICS:

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

SIST EN ISO 10328:2006 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10328

October 2006

ICS 11.040.40

English Version

Prosthetics - Structural testing of lower-limb prostheses - Requirements and test methods (ISO 10328:2006)

Prothèses - Essais portant sur la structure des prothèses de membres inférieurs - Exigences et méthodes d'essai (ISO 10328:2006)

Prothetik - Prüfung der Struktur von Prothesen der unteren Gliedmaßen - Anforderungen und Prüfverfahren (ISO 10328:2006)

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

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Ref. No. EN ISO 10328:2006: E

Foreword

This document (EN ISO 10328:2006) 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 10328:2006 has been approved by CEN as EN ISO 10328:2006 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.
21	13.3 k)	

INTERNATIONAL STANDARD

ISO 10328

First edition
2006-10-01

Prosthetics — Structural testing of lower-limb prostheses — Requirements and test methods

Prothèses — Essais portant sur la structure des prothèses de membres inférieurs — Exigences et méthodes d'essai

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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 10328 was prepared by Technical Committee ISO/TC 168, *Prosthetics and orthotics*.

This first edition cancels and replaces the eight parts of the first edition (ISO 10328-1:1996 to ISO 10328-8:1996), which have been technically revised and combined into one single document.