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IRISH STANDARD

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EXTERNAL LIMB PROSTHESES AND EXTERNAL ORTHOSES - REQUIREMENTS AND TEST METHODS (ISO 22523:2006)

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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.

EUROPEAN COMMITTEE FOR STANDARDIZATION
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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of an identical text or by endorsement, at the latest by April 2007, and conflicting national standards shall be withdrawn at the latest by April 2007.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)	