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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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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*.

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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.