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**BS EN ISO 22675:2016**



**BSI Standards Publication**

# **Prosthetics — Testing of ankle-foot devices and foot units — Requirements and test methods (ISO 22675:2016)**

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This British Standard is the UK implementation of EN ISO 22675:2016. It supersedes BS EN ISO 22675:2006 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/168, Prosthetics and orthotics.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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**Compliance with a British Standard cannot confer immunity from legal obligations.**

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## Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods (ISO 22675:2016)

Prothèses - Essais d'articulations cheville-pied et  
unités de pied - Exigences et méthodes d'essai (ISO  
22675:2016)

Prothetik - Prüfung von Knöchel-Fuß-Pasteilen und  
Fußeinheiten - Anforderungen und Prüfverfahren (ISO  
22675:2016)

This European Standard was approved by CEN on 12 May 2016.

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**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels**

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## European foreword

This document (EN ISO 22675:2016) 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of an identical text or by endorsement, at the latest by December 2016, and conflicting national standards shall be withdrawn at the latest by December 2016.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 22675:2006.

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, B, C or D, 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, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

### Endorsement notice

The text of ISO 22675:2016 has been approved by CEN as EN ISO 22675:2016 without any modification.

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**Annex ZA**  
(informative)  
**Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC [OJ L 169] aimed to be covered**

This European standard has been prepared under a Commission's standardization request 'M/023 concerning the development of European standards related to medical devices' to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive, and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk has to be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

**Table ZA.1 — Correspondence between this European standard and Annex I of Directive 93/42/EEC [OJ L 169]**

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
9.1	5	With respect to use in combination with other devices or equipment.
9.1	19 and 20	With respect to any restrictions on use which shall be indicated on the label or in the instructions for use.
12.7.1	5, 7, 8, 9, 10, 15, 16 and 17	Only covered for mechanical strength.
13.1	5, 19, and 20.4	Essential requirement 13.1 is not fully covered here; only the aspects of classification are addressed.

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Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
13.3 b)	20	Only covered for classification of the use of the device.
13.3 k)	20.2	Only covered for limitations due to body mass limit and specific activities undertaken by the user.

**WARNING 1:** Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

**WARNING 2:** Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 168, *Prosthetics and orthotics*.

This second edition cancels and replaces the first edition ISO 22675:2006 which has been technically revised with the following changes:

- a) Test loading levels P7 and P8 have been introduced in [Table 10](#), Table A.1, [Table C.1](#), [Table C.2](#) and the clauses pointing at these tables have been updated. Additional information on P7 and P8 is given in Annex A.1;
- b) [Table 9](#) has been revised
- c) [Annex C](#) has changed from informative to normative

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## Introduction

This International Standard offers alternatives to the structural tests on ankle-foot devices and foot units specified in 17.2 of ISO 10328:2016, 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 10328:2016;
- 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 10328:2016. 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.

**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).

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# 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 ISO 22523:2006 through submission to the relevant tests of ISO 10328:2006, 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** 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 10328:2016, 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 10328:2016.

## 2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.