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STN	**Protetika** **Skúšanie pomôcok členok-noha a častí nohy** **Požiadavky a skúšobné metódy** **(ISO 22675: 2024)**	**STN** **EN ISO 22675** 84 1003

Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods (ISO 22675:2024)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 07/25

Obsahuje: EN ISO 22675:2025, ISO 22675:2024

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EN ISO 22675

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Supersedes EN ISO 22675:2016

English Version

Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods (ISO 22675:2024)

Prothèses - Essais d'articulations cheville-pied et unités de pied - Exigences et méthodes d'essai (ISO 22675:2024)

Prothetik - Prüfung von Knöchel-Fuß-Passteilen und Fußeinheiten - Anforderungen und Prüfverfahren (ISO 22675:2024)

This European Standard was approved by CEN on 19 November 2024.

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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 CEN-CENELEC Management Centre has the same status as the official versions.

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

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Ref. No. EN ISO 22675:2025 E

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European foreword

This document (EN ISO 22675:2025) has been prepared by Technical Committee ISO/TC 168 "Prosthetics and orthotics" in collaboration with Technical Committee CEN/TC 293 “Assistive products and accessibility” 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of an identical text or by endorsement, at the latest by November 2025, and conflicting national standards shall be withdrawn at the latest by November 2025.

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

This document supersedes EN ISO 22675:2016.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 22675:2024 has been approved by CEN as EN ISO 22675:2025 without any modification.

Annex ZA
(informative)

Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up.

Once this standard is cited in the Official Journal of the European Union under that Regulation, 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 General Safety and Performance Requirements of that Regulation, and associated EFTA Regulations.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences shall be indicated in this Annex Z. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this standard can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the standard can only support European regulatory requirements to the extent of the scope of the European regulation for medical devices (EU) 2017/745).

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 Regulation (EU) 2017/745. This means that risks have to be ‘reduced as far as possible’, ‘reduced to the lowest possible level’, ‘reduced as far as possible and appropriate’, ‘removed or reduced as far as possible’, ‘eliminated or reduced as far as possible’, ’removed or minimized as far as possible’, or ‘minimized’, according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer’s policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

NOTE 3 When a General Safety and Performance 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 Regulation (EU) 2017/745 [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks/Notes
14.1	5, 9, 19 and 20	Covered with respect to mechanical strength of the ankle-foot device or foot unit in combination with the remainder of a prosthetic structure. Risks arising from misconnections are not covered. Covered with respect to any restrictions on use which shall be indicated on the identifier or in the instructions for use.
20.1	5, 7, 8, 9, 10, 15, 16 and 17	Only covered for mechanical strength.
23.1	19 and 20.3	General Safety and Performance Requirement 23.1 is not fully covered here; only the aspects of classification are addressed.
23.2 b)	19 and 20	Only covered for classification of the use of the device.
23.2 m)	7, 19 and 20.1	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.

Table ZA.2 — Normative references from Clause 2 of this document and their corresponding European publications

Column 1 Reference in Clause 2	Column 2 International Standard Edition	Column 3 Title	Column 4 Corresponding European Standard Edition
ISO 7000	ISO 7000:2019	Graphical symbols for use on equipment — Registered symbols	None For applicable standard edition see Column 2
ISO 8549-1	ISO 8549-1:2020	Prosthetics and orthotics — Vocabulary — Part 1: General terms for external limb prostheses and external orthoses	None For applicable standard edition see Column 2
ISO 10328:2016	ISO 10328:2016	Prosthetics — Structural testing of lower-limb prostheses — Requirements and test methods	EN ISO 10328:2016
ISO 22523:2006	ISO 22523:2006	External limb prostheses and external orthoses — Requirements and test methods	EN ISO 22523:2006
IEC 60417	IEC 60417:2002 DB	Graphical symbols for use on equipment	None For applicable standard edition see Column 2

The documents listed in the Column 1 of Table ZA.2, in whole or in part, are normatively referenced in this document, i.e. are indispensable for its application. The achievement of the presumption of conformity is subject to the application of the edition of Standards as listed in Column 4 or, if no European Standard Edition exists, the International Standard Edition given in Column 2 of Table ZA.2.

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.

International Standard

ISO 22675

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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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 document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 168, *Prosthetics and orthotics,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 293, *Assistive products and accessibility,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 22675:2016), which has been technically revised.

The main changes are as follows:

— test Ranges (R) have been introduced;

— test loading levels P7 and P8 have been introduced in Table 5, 8, 9, 10, 11 and A.1 and the clauses pointing at these tables have been updated;

— Former Annex C has been deleted and integrated in main text;

— Subclause 15.2 has been updated;

— Subclause 16.5 has been added.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document offers alternatives to the structural tests on ankle-foot devices and foot units specified in ISO 10328:2016, 17.2, 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 document 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, the potential of the general concept applied to the test procedures specified in this document allows other applications directed to the assessment of specific performance characteristics of ankle-foot devices and foot units that can 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 ISO/TR 22676.

International Standard **ISO 22675:2024(en)**

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

WARNING — This document 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.

1 Scope

This document primarily specifies a cyclic test procedure for ankle-foot devices and foot units of external lower limb prostheses, these differ in the potential to realistically simulate those loading conditions of the complete stance phase of walking from heel strike to toe-off which is 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 document 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), 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.

These loading conditions 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 document are characterized by standardized formats of these loading and locomotion profiles, applied by the cyclic and static test procedures to each sample of ankle-foot device or foot unit submitted for test.

This document specifies Test Ranges (R) by specifying locomotion profiles for the cyclic test in relation to the intended use. According to the concept of the tests of this document, each sample of ankle-foot device or foot unit submitted for test is, nevertheless, free to develop its individual performance under load.

This document is suitable for the assessment and testing of prosthetic ankle-foot devices and foot units with the strength requirements specified in 4.4 of ISO 22523:2006 (see NOTE). 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 10328:2016, need not be retested to this document.

NOTE The lines of action of the heel and forefoot forces generated by the static test procedure for Test Range 4 (R4) specified in this document approach those determining the sagittal plane loading of the test loading conditions I and II for the principal structural tests referring to 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 are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

ISO 8549-1, *Prosthetics and orthotics — Vocabulary — Part 1: General terms for external limb prostheses and external orthoses*

ISO 10328:2016, *Prosthetics — Structural testing of lower-limb prostheses — Requirements and test methods*

ISO 22523:2006, *External limb prostheses and external orthoses — Requirements and test methods*

IEC 60417, *Graphical symbols for use on equipment*