

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

Oznámením tejto normy sa ruší

STN EN ISO 22675 (84 1003) z decembra 2016

140850

Úrad pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky, 2025

Slovenská technická norma a technická normalizačná informácia je chránená zákonom č. 60/2018 Z. z. o technickej normalizácii v znení neskorších predpisov.

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 22675

May 2025

ICS 11.040.40

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-Pasteilen und
Fußeinheiten - Anforderungen und Prüfverfahren (ISO
22675:2024)

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

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EN ISO 22675:2025 (E)**Contents**

Page

European foreword.....	3
Annex ZA (informative) Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered.....	4

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of an identical text or by endorsement, at the latest by November 2025, and conflicting national standards shall be withdrawn at the latest by November 2025.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.

EN ISO 22675:2025 (E)**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 [O] 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.

EN ISO 22675:2025 (E)**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*

Third edition 2024-12

ISO 22675:2024(en)



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Published in Switzerland

ISO 22675:2024(en)**Contents**

Page

Foreword	vi
Introduction	vii
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Symbols	3
5 Strength and related performance requirements and conditions of use	3
6 Coordinate system and test configurations	4
6.1 General	4
6.2 Origin and axes of the coordinate system	4
6.3 Reference points	5
6.4 Test force F	6
6.5 Line of application of test force F	6
6.6 Lines of action of resultant reference forces F_{R1} and F_{R2}	6
6.7 Longitudinal axis of the foot and effective ankle joint centre	6
6.7.1 General	6
6.7.2 Longitudinal axis of the foot	6
6.7.3 Effective ankle-joint centre C_A	6
7 Test loading conditions and test loading levels	8
7.1 Test loading conditions	8
7.2 Test loading levels and Test Ranges (R)	8
8 Values of test forces, dimensions and cycles	9
9 Compliance	17
9.1 General	17
9.2 Particular arrangements and requirements concerning the part required to connect an ankle-foot device or foot unit to the remainder of a prosthetic structure	18
9.2.1 Arrangements for testing	18
9.2.2 Requirements for claiming compliance	18
9.3 Number of tests and test samples required to claim compliance with this document	18
9.4 Multiple use of test samples	18
9.4.1 General	18
9.4.2 Restriction	19
9.5 Testing at particular test loading levels not specified in this document	19
10 Test samples	20
10.1 Selection of test samples	20
10.1.1 General	20
10.1.2 Selection of ankle-foot devices and foot units of appropriate size of foot	20
10.2 Types of test sample	21
10.2.1 Complete structure	21
10.2.2 Partial structure	21
10.3 Preparation of test samples	21
10.4 Identification of test samples	21
10.5 Alignment of test samples	22
10.6 Worst-case alignment position of test samples	22
11 Responsibility for test preparation	24
12 Test submission document	25
12.1 General requirements	25
12.2 Information required for test samples	25
12.3 Information required for tests	26
12.3.1 General	26

ISO 22675:2024(en)

	12.3.2	For all tests.....	26
	12.3.3	For the static proof test and the static ultimate strength test.....	26
	12.3.4	For the static ultimate strength test.....	26
	12.3.5	For the cyclic test.....	26
13	Equipment.....		27
	13.1	General.....	27
	13.2	End attachments.....	27
	13.2.1	General.....	27
	13.2.2	Proof test of end attachments.....	27
	13.3	Jig.....	29
	13.4	Test equipment.....	30
	13.4.1	Test equipment to perform static heel and forefoot loading.....	30
	13.4.2	Test equipment to perform cyclic loading.....	31
14	Accuracy.....		37
	14.1	General.....	37
	14.2	Accuracy of equipment.....	38
	14.3	Accuracy of procedure.....	38
15	Test principles.....		38
	15.1	General.....	38
	15.2	Static test procedure.....	39
	15.3	Cyclic test procedure.....	42
16	Test procedures.....		42
	16.1	Test loading requirements.....	42
	16.1.1	Preparation for test loading.....	42
	16.1.2	Test loading conditions.....	45
	16.2	Static proof test.....	46
	16.2.1	Test method.....	46
	16.2.2	Performance requirement.....	48
	16.2.3	Compliance conditions.....	48
	16.3	Static ultimate strength test.....	50
	16.3.1	Test method.....	50
	16.3.2	Performance requirements.....	52
	16.3.3	Compliance conditions.....	52
	16.4	Cyclic test.....	53
	16.4.1	Test method.....	53
	16.4.2	Performance requirements.....	56
	16.4.3	Compliance conditions.....	56
	16.5	Separate static test in torsion.....	59
	16.5.1	General.....	59
	16.5.2	Purpose of test.....	59
	16.5.3	Test method.....	59
	16.5.4	Performance requirements.....	60
	16.5.5	Compliance conditions.....	60
17	Test laboratory/facility log.....		61
	17.1	General requirements.....	61
	17.2	Specific requirements.....	61
18	Test report.....		61
	18.1	General requirements.....	61
	18.2	Specific requirements.....	62
	18.3	Options.....	62
19	Classification and designation.....		62
	19.1	General.....	62
	19.2	Example of classification and designation.....	62
20	Identifier.....		63
	20.1	General.....	63

ISO 22675:2024(en)

20.2	Identifier layout.....	63
20.3	Identifier placement.....	63
Annex A	(informative) Reference data for the specification of the test loading conditions and test loading levels of this document.....	64
Annex B	(informative) Guidance on the application of an alternative static ultimate strength test.....	73
Annex C	(informative) Summary of the records entered in the test laboratory/facility log.....	74
Annex D	(informative) Information on ISO/TR 22676.....	79
Annex E	(informative) Background data (reduced) of the six-minute walk test for adults	90
Bibliography		91

ISO 22675:2024(en)

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).

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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.

ISO 22675:2024(en)

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.

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 22675:2024(en)

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*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN