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Small-bore connectors for liquids and gases in healthcare applications —

Part 2: Connectors for respiratory applications

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé —

Partie 2: Raccords destinés à des applications respiratoires

Reference number
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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Foreword

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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).

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This document was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for products with a health purpose including medical devices*, in collaboration with Technical Committee IEC/SC 62D, *Particular medical equipment, software, and systems*, and with the European Committee for Standardization (CEN) Technical Committee CEN/CLC/JTC 3, *Quality management and corresponding general aspects for medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 80369 series can be found on the ISO website.

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

The *small-bore connectors* specified in this document conform with the requirements for *non-interconnectable* characteristics of ISO 80369-1.

This document includes design and performance requirements for *small-bore connectors* for the respiratory *application*.

It is recognised that the *small-bore connectors* specified in this document might not be suitable for some *medical devices* or *accessories* within this *application*.

Annex A contains guidance or rationale on the requirements in this document.

This document has been prepared to support the essential principles for *medical device* or *accessories* incorporating respiratory *application small-bore connectors* according to the International Medical Device Regulators Forum (IMDRF). See Annex H.

In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

In this document, the following verbal forms are used:

— "shall" indicates a requirement;

— "should" indicates a recommendation;

— "may" indicates a permission;

— "can" indicates a possibility or capability; and

— "must" is used to express an external constraint.

NOTE This document uses italic type to distinguish defined terms from the rest of the text. It is important for the correct understanding of this document that those defined terms are identifiable throughout the text of this document. A list of the terms in italics is given in Annex I.

Small-bore connectors for liquids and gases in healthcare applications —

Part 2:
Connectors for respiratory applications

1 Scope

This document specifies the design and dimensions for two *small-bore connectors* intended to be used for *connections* in respiratory *applications* of *medical devices* and *accessories*. One *connector* (R1) is intended for use on *medical devices* and *accessories* subjected to pressures up to 15 kPa (e.g. a *breathing system*). The other *connector* (R2) is intended for use on *medical devices* and *accessories* subjected to higher pressures between 15 kPa and 600 kPa (e.g. oxygen therapy tubing).

NOTE 1 The pressure is related to pressure available at the source to which the *medical device* is connected.

NOTE 2 The intended *application* does not preclude the use of other *connectors* on *medical devices* or *accessories* within this *application*.

NOTE 3 Requirements for alternative connectors for this intended application are specified in ISO 80369-1.

This document does not specify requirements for the *medical devices* or *accessories* that use these *connectors*. Such requirements are given in device-specific standards.

NOTE 4 If a device-specific standard does not exist, the performance and material requirements specified in ISO 80369-1 can be used as guidance.

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 178, *Plastics — Determination of flexural properties*

ISO 527 (all parts), *Determination of tensile properties*

ISO 6892-1:2019, *Metallic materials — Tensile testing — Part 1: Method of test at room temperature*

ISO 14971:2019, *Medical devices — Application of risk management to medical devices*

ISO 80369-1:2018, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80369-7:2021, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

ISO 80369-20:2015, *Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods*

ASTM D638-22, *Standard Test Method for Tensile Properties of Plastics*

ASTM D790-17, *Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14971, ISO 80369-1, ISO 80369-7, ISO 80369-20 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org

NOTE For convenience, the sources of all defined terms that appear in italics in this document are given in Annex I.

3.1
auxiliary dimension
dimensions derived from other dimensions given for information purposes only

[SOURCE: ISO 10209:2022, 3.3.2]

3.2
breathing system
pathways through which gas flows to or from the *patient* at *respiratory pressures* and continuously or intermittently in fluid communication with the *patient's* respiratory tract during any form of artificial ventilation or respiratory therapy

[SOURCE: ISO 4135:2022, 3.6.1.1, modified — Notes 1 to 5 to entry have been removed.]

3.3
cone
<*connector*> with external sealing surface

Note 1 to entry: The sealing surface need not be conical.

Note 2 to entry: This type of *connector* was previously referred to as male.

3.4
medical gas pipeline system
complete system which comprises a supply system, a monitoring and alarm system and a distribution system with terminal units at the points where medical gases or vacuum are required

[SOURCE: ISO 7396-1:2016, 3.36]

3.5
normal use
operation, including routine inspection and adjustments by any *user*, and stand-by, according to the instructions for use

Note 1 to entry: *Normal use* should not be confused with *intended use*. While both include the concept of use as intended by the *manufacturer*, *intended use* focuses on the medical purpose while *normal use* incorporates not only the medical purpose, but maintenance, service, transport, etc. as well

[SOURCE: IEC 60601-1:2005, 3.71, modified — replaced '*operator*' with '*user*'.]

3.6
socket
<*connector*> with internal sealing surface

Note 1 to entry: This type of *connector* was previously referred to as female.

3.7
user
person interacting with (i.e. operating or handling) the *medical device*

Note 1 to entry: There can be more than one *user* of a *medical device*.

Note 2 to entry: Common *users* include clinicians, *patients*, cleaners, maintenance and service personnel.

[SOURCE: IEC 62366-1:2015, 3.24]

4 Non-interconnectability requirements

Small-bore connectors made in conformance with this document conform with the requirements of ISO 80369-1.

NOTE 1 The reference *connectors* for evaluation of the *non-interconnectable* characteristics are described in Annex C.

NOTE 2 The summary of *medical devices* and their attributes with *connections* within this *application* is provided in informative Annex D.

NOTE 3 The summary of the usability requirements for *connectors* for this *application* is provided in informative Annex E.

NOTE 4 The summary of criteria and requirements for *connectors* for this *application* is provided in informative Annex F.

NOTE 5 The summary of assessment of the design of *connectors* for this *application* according to ISO 80369-1:2018, 6.1, is contained in informative Annex G.

NOTE 6 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745[8].

5 Material requirements

NOTE There is rationale for the option to apply either the ISO or the ASTM standards to confirm the modulus of elasticity contained in Annex A.

a) R1 and R2 *small-bore connectors* shall be made of materials with a nominal modulus of elasticity either in flexure or in tension greater than 700 MPa.

b) Surfaces, other than those necessary to ensure *non-interconnectable* characteristics, need not comply with the modulus of elasticity requirement.

Check conformity by applying the tests of ASTM D638-22, the ISO 527 series, ASTM D790-17 or ISO 178 or for metallic materials, the tests of ISO 6892-1.

6 Dimensions and tolerances

6.1 R1 *small-bore connectors*

Small-bore connectors intended for use on respiratory *medical devices* and *accessories* at pressures less than 150 hPa (15 kPa) above ambient shall conform with the dimensions and tolerances as given in

a) Figure B.1 and Table B.1 for a R1 *cone connector*, and

b) Figure B.2 and Table B.2 for a R1 *socket connector*.

Check conformity by confirming the relevant dimensions and tolerances specified in Annex B.

6.2 R2 *small-bore connectors*

Small-bore connectors intended to be used on respiratory *medical devices* and *accessories* at pressures between 15 kPa and 600 kPa above ambient shall conform with the dimensions and tolerances given in

a) Figure B.3 and Table B.3 for a R2 *cone connector*, and

b) Figure B.4 and Table B.4 for a R2 *socket connector*.

Check conformity by confirming the relevant dimensions and tolerances specified in Annex B.

7 Performance requirements

7.1 Leakage by pressure decay

NOTE Annex A contains guidance or rationale for this subclause.

a) R1 and R2 *small-bore connectors* shall be evaluated for fluid leakage using the leakage by pressure decay *test method*.

b) When tested over a hold period between 30 s and 35 s using air as the medium,

   1) a R1 *small-bore connector* shall not exceed a leakage rate of 0,000 25 Pa·m^3/s while being subjected to an applied pressure of between 12,5 kPa and 15,0 kPa, and

   2) a R2 *small-bore connector* shall not exceed 0,005 Pa·m^3/s while being subjected to an applied pressure of between 600 kPa and 640 kPa.

Check conformity by applying the tests of ISO 80369-20:2015, Annex B, while using the leakage reference *connector* specified in Annex C (Figures C.1, C.3, C.8, and C.10, as appropriate). A greater applied pressure or a longer hold period may be used.

7.2 Sub-atmospheric pressure air leakage

a) A R1 *connector* shall not exceed a leakage flowrate of 0,000 05 Pa·m^3/s while being subjected to an applied sub atmospheric pressure of between 3,0 kPa and 5,0 kPa over a hold period of between 25 s and 35 s.

b) A R2 *connector* shall not exceed a leakage flowrate of 0,005 Pa·m^3/s while being subjected to an applied sub atmospheric pressure of between 35,0 kPa and 45,0 kPa over a hold period of between 20 s and 30 s.

Check conformity by applying the tests of ISO 80369-20:2015, Annex D, while using the leakage reference *connector* specified in Annex C (Figures C.1, C.3, C.8, and C.10, as appropriate). A greater applied sub-atmospheric pressure may be used.

7.3 Stress cracking

R1 and R2 *small-bore connectors* shall meet the requirements of 7.1 and 7.2 after being subjected to the stresses specified in ISO 80369-20:2015, Annex E.

Check conformity by applying the tests of ISO 80369-20:2015, Annex E, while using the stress cracking reference *connector* specified in Annex C (Figures C.1, C.3, C.8, and C.10, as appropriate).

7.4 Resistance to separation from axial load

R1 and R2 *small-bore connectors* shall not separate from the reference *connector* over a hold period between 10 s and 15 s while being subjected to a disconnection applied axial force between 32 N and 35 N.

Check conformity by applying the tests of ISO 80369-20:2015, Annex F, while using the separation from axial load reference *connector* specified in Annex C (Figures C.2, C.4, C.9, and C.11, as appropriate). A greater disconnection applied axial force or a longer hold period may be used.

7.5 Resistance to separation from unscrewing

R1 and R2 *connectors* shall not separate from the reference *connector* for a hold period between 10 s and 15 s while being subjected to an unscrewing torque of between 0,018 N·m to 0,020 N·m.

Check conformity by applying the tests of ISO 80369-20:2015, Annex G, while using the separation from unscrewing reference *connector* specified in Annex C (Figures C.1, C.3, C.8, and C.10, as appropriate). A greater applied unscrewing torque or a longer hold period may be used.

7.6 Resistance to overriding

R1 and R2 *small-bore connectors* shall not override the threads or lugs of the reference *connector* while being subjected to an applied torque of

a) between 0,15 N·m to 0,17 N·m over a hold period between 5 s and 10 s for a R1 *connector*, and

b) between 0,22 N·m to 0,25 N·m over a hold period between 5 s and 10 s for a R2 *connector*.

Check conformity by applying the tests of ISO 80369-20:2015, Annex H, while using the resistance to overriding reference *connector* specified in Annex C (Figures C.2, C.4, C.9, and C.11, as appropriate). A greater applied torque or a longer hold period may be used.

7.7 Disconnection by unscrewing

R1 and R2 *small-bore connectors* shall separate from the reference *connector* with an applied unscrewing torque of no greater than 0,35 N·m.

Check conformity by applying the tests of ISO 80369-20:2015, Annex I, while using the disconnection by unscrewing the reference *connector* specified in Annex C (Figures C.1, C.3, C.8, and C.10, as appropriate).

Annex A
(informative)

Rationale and guidance

A.1 General guidance

This Annex provides a rationale for some requirements of this document and is intended for those who are familiar with the subject of this document, but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale for the present requirements will facilitate any revision of this document necessitated by those developments.

A.2 Rationale for particular clauses and subclauses

The clauses and subclauses in this Annex have been numbered to correspond to the numbering of the clauses and subclauses of this document to which they refer. The numbering is, therefore, not consecutive.

Clause 1 Scope

In 2000, a Task Group of the European standards organization, CEN, proposed a strategy to reduce incidents of accidental misconnection of *patient* therapy lines by the use of a series of *non-interconnectable connectors*, differentiated by design, for use in different medical *applications*. The strategy reserves the use of *Luer connectors* solely for use in *medical devices* used to access the vascular system or for hypodermic syringes so that they can achieve their intended function.[7] The *connectors* specified in this document are intended to be used on respiratory *medical devices*.

Manufacturers and *responsible organizations* are encouraged to report their experience with the *small-bore connectors* specified in this document to their national standards body (see the last paragraph of the Foreword), so that it can consider this feedback during the revision of the relevant part of the ISO 80369 series.

Subclause 6.1 Leakage by pressure decay

The test pressures chosen are the worst-case pressures that can be generated under a *single fault condition* for a *breathing system* for the R1 *connector* and for a *medical gas pipeline system* for the R2 *connector*.

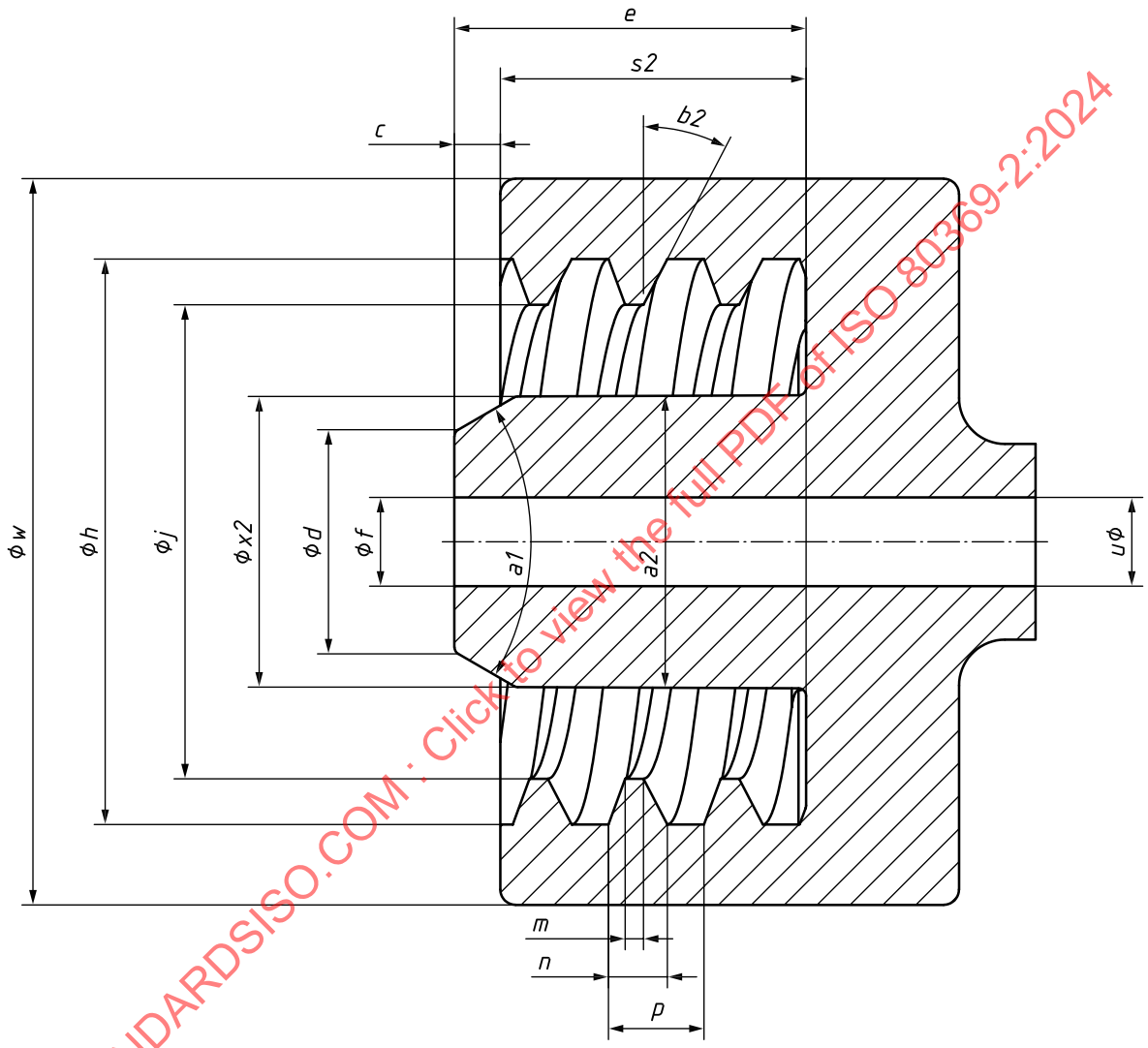
Clause 5 Material requirements

It was determined although several fundamental differences exist between ASTM D 638 Standard Test Method of Tensile Properties of Plastics and ISO 527 Plastics - Determination of Tensile Properties, the actual test results can be quite similar. Test data for both test methods have been gathered by an interlaboratory testing provider and the summary statistics of the two groups were compared. The thermoplastic resins tested in this study included polycarbonate (PC), polybutylene terephthalate (PBT), acrylonitrilebutadiene-styrene (ABS) and high impact polystyrene (HIPS). All resins were unfilled, unreinforced, and uncoloured. The following properties were analysed: Tensile Stress at Yield, Tensile Stress at Break, Elongation at Yield, and Modulus of Elasticity. After removing outliers, the data from the remaining labs were analysed. The strength of agreement between ISO data and ASTM data varied depending on the property and material used. There were surprising similarities for modulus of elasticity since different speeds of testing and calculation methods were used.

Annex B
(normative)

Small-bore connectors for *respiratory applications*

Table B.1 contains the dimensions for Figure B.1.



The *cone connector* shows a permanently connected internally threaded lock fitting. A rotatable internally threaded lock fitting may be used.

Figure B.1 — R1 *cone small-bore connector*

Table B.1 — R1 *cone small-bore connector* dimensions

Dimensions in millimetres unless otherwise indicated

R1 *cone connector*				
Reference	**Designation**	**Dimension**		
		Minimum	***Nominal***	**Maximum**
*a*1	Angle of the sealing *cone*, in degrees	58,0°	—	62,0°
*a*2	Angle of the draft allowance, in degrees	—	—	1,00°
*b*2	Angle of internal thread profile on the bearing surface against separation, in degrees	26,5°	—	28,5°
c[a]	Protrusion of the *cone* post geometry face from the face of grip	0 635	—	0 889
Ø*d*	Outside diameter at the tip of the *cone* post geometry	3 600	—	3 700
e	Depth of the *cone* post geometry	5 715	—	—
Ø*f*	Inside diameter at the entrance face of the fluid lumen	—	—	2 850
Ø*h*	Major inside thread diameter of the *cone* lock *connector* (diameter at thread root)	9 267	—	9 521
Ø*j*	Minor inside thread diameter of the *cone* lock *connector*, (diameter at thread crest)	7 747	—	8001
m	Width of the thread form at the crest of a *cone* lock *connector*	0 229	—	0 381
n	Width of the thread form at the root of *cone* lock *connector*	0 873	—	1 083
p	*Nominal* pitch of double-start, right-hand thread of *cone* lock *connector*	1 508	—	1668
*s*2	Thread length from open end of the grip	5 080	—	—
Ø*u*	Inner diameter of the fluid lumen	—	—	2 850
Ø*w*	Outside diameter of the smallest cylinder that encompasses the outside surfaces of the external features of the collar	11 811	—	12 319
Ø*x*2	Diameter at the base of the sealing *cone*	4 851	—	4 953

[a] This dimension is when the floating or rotatable collar is positioned fully toward tip of the *connector*.

Table B.2 contains the dimensions for Figure B.2.

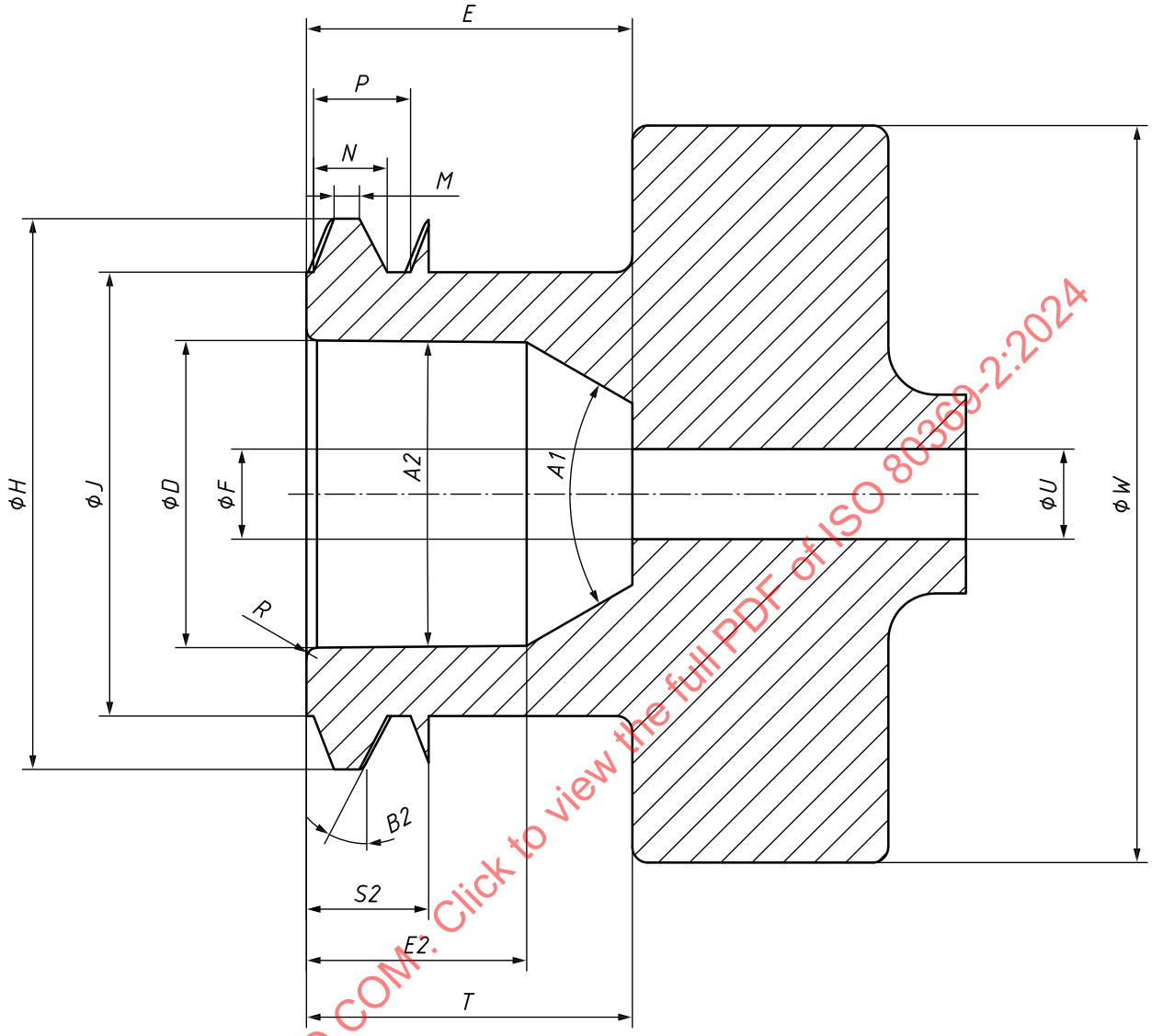


Figure B.2 — R1 *socket small-bore connector*

Table B.2 — R1 *socket small-bore connector* dimensions

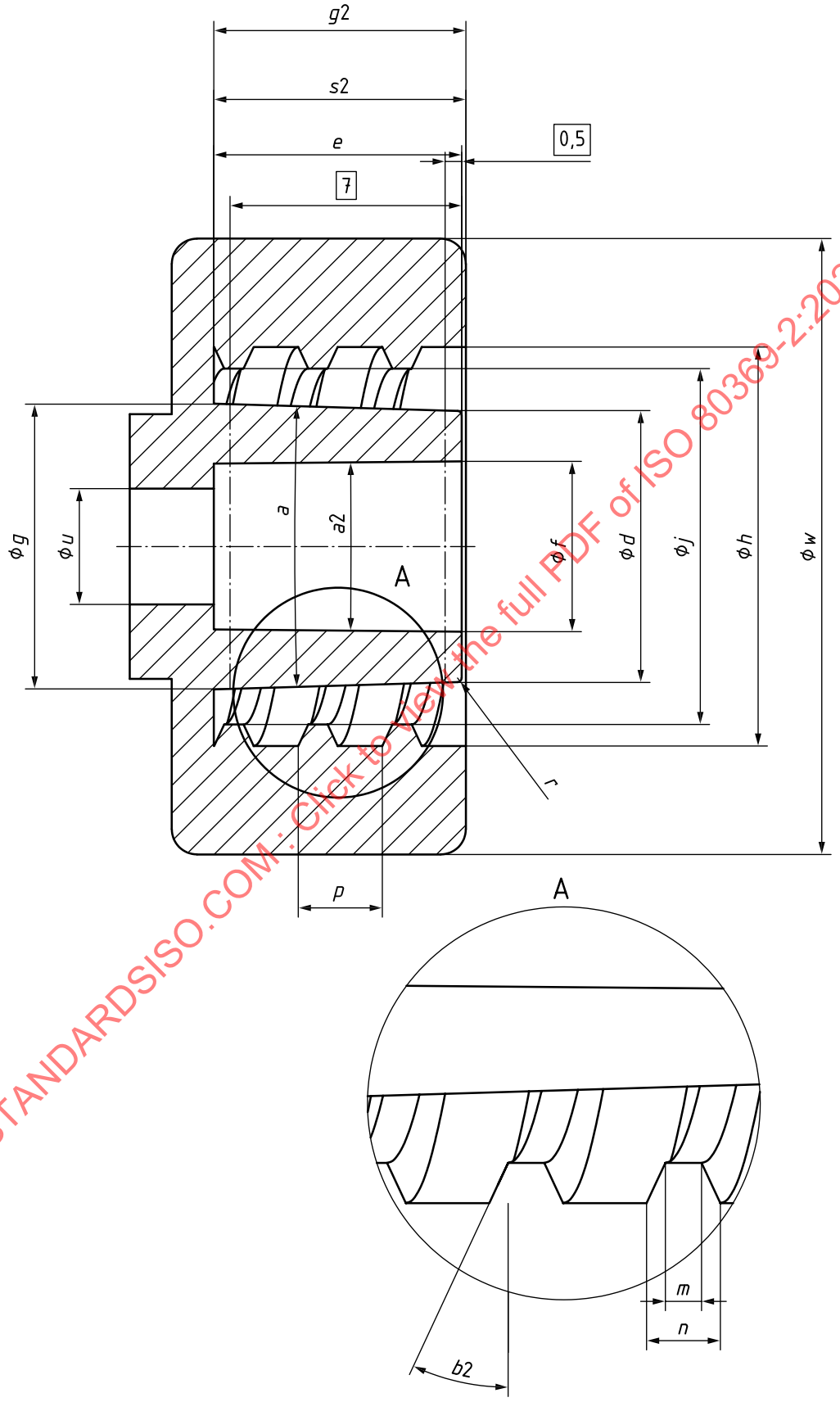
Dimensions in millimetres unless otherwise indicated

R1 *socket connector*				
Reference	**Designation**	**Dimension**		
		Minimum	***Nominal***	**Maximum**
A1	Angle of the sealing *cone*, in degrees	58,0°	—	62,0°
A2	Angle of the draft allowance, in degrees	—	—	1,00°
B2	Angle of external thread profile on the bearing surface against separation, in degrees	26,5°	—	28,5°
ØD	Inside diameter at the open end of the *socket* geometry	5 060	—	5 150
E	Depth of the *socket* geometry	5 207	—	5 461
E2	Depth to the base of the sealing *cone*	3 446		3766
ØF	Inside diameter at the entrance face of the fluid lumen	—	—	2 850

Table B.2 *(continued)*

R1 *socket connector*				
Reference	**Designation**	**Dimension**		
		Minimum	***Nominal***	**Maximum**
ØH	Major outside thread diameter of the *socket* lock *connector*, (diameter at thread crest)	8 887	—	9 141
ØJ	Minor outside thread diameter of the *socket* lock *connector*, (diameter at thread root)	7 137	—	7 391
M	Width of the thread form at the crest of a *socket* lock *connector*	0 384	—	0 444
N	Thread width of *socket* lock *connector* at root	1 177	—	1 237
P	*Nominal* pitch of double-start, right-hand thread of the *socket* lock *connector*	1 461	—	1 715
R	Radius or chamfer at the entrance of the *socket* taper	—	—	0,25
*S*2	Thread length from open end of the *socket* taper	2 670	—	—
T	Distance from the *connector* face to the beginning of the grip geometry	5 207	—	—
ØU	Inner diameter of the fluid lumen (*auxiliary dimension*)	—	(1,950)	—
ØW	Diameter of the smallest cylinder that encompasses the outside surfaces of the external features of the collar	11 811	—	12 319

Table B.3 contains the dimensions for Figure B.3.



The *cone connector* shows a permanently connected internally threaded lock fitting. A rotatable internally threaded lock fitting may be used.

Figure B.3 — R2 *cone small-bore connector*

Table B.3 — R2 *cone small-bore connector* dimensions

Dimensions in millimetres unless otherwise indicated

R2 *cone connector*				
Reference	**Designation**	**Dimension**		
		Minimum	***Nominal***	**Maximum**
a	Angle of taper, (6 % taper *nominal*) degrees, (*auxiliary dimension*)	—	(3,44°)	—
*a*2	Angle of taper inside tip of cone taper (not yet shown on figure)	0°	—	1,0°
*b*2	Angle of internal thread profile on the bearing surface against separation, in degrees	24,0°	—	26,0°
Ø*d*	Outside diameter at the tip of the *cone* taper at 0 500 (basic dimension) from the tip (small end) of the *cone* taper	8 164	—	8 266
e	Length of *cone* taper and length of inside diameter to Ø*u*	7 366	—	7 620
Ø*f*	Inside diameter at the tip of the *cone* taper	5 300	—	5 609
Ø*g*	Outside diameter of the larger end of the *cone* taper at 7 000 (basic dimension) from the tip (small end) of the *cone* taper	8554	—	8 656
*g*2 [a]	Front of grip to interior base of thread/*cone* taper	7 493	—	7 747
Ø*h*	Major inside thread diameter of the *cone* lock *connector* (diameter at thread root)	11 927	—	12 181
Ø*j*	Minor inside thread diameter of the *cone* lock *connector*, (diameter at thread crest)	10 657	—	10 881
m	Width of the thread form at the crest of a *cone* lock *connector*	0 554	—	0 614
n	Thread width of *cone* lock *connector* at root	1 161	—	1 221
p	*Nominal* pitch of double-start, right-hand thread of *cone lock connector* – 5 mm lead	2 413	—	2 667
r	Radius or chamfer at the tip of the *cone* taper	0 000	—	0 250
*s*2	Thread length from taper base of *cone* lock *connector*	7 493	—	7 747
Ø*u*	Inner diameter of the fluid lumen	3 375	—	3 629
Ø*w*	Diameter of the smallest cylinder that encompasses the outside surfaces of the external features of the collar [b]	18 340	—	18 872

[a] This dimension is when the floating or rotatable collar is positioned fully toward tip of the *connector*.

[b] The minimum value of *w* shall be maintained for the length of 1,00 mm and the maximum value shall be maintained for the length of *e*.

Table B.4 contains the dimensions for Figure B.4.

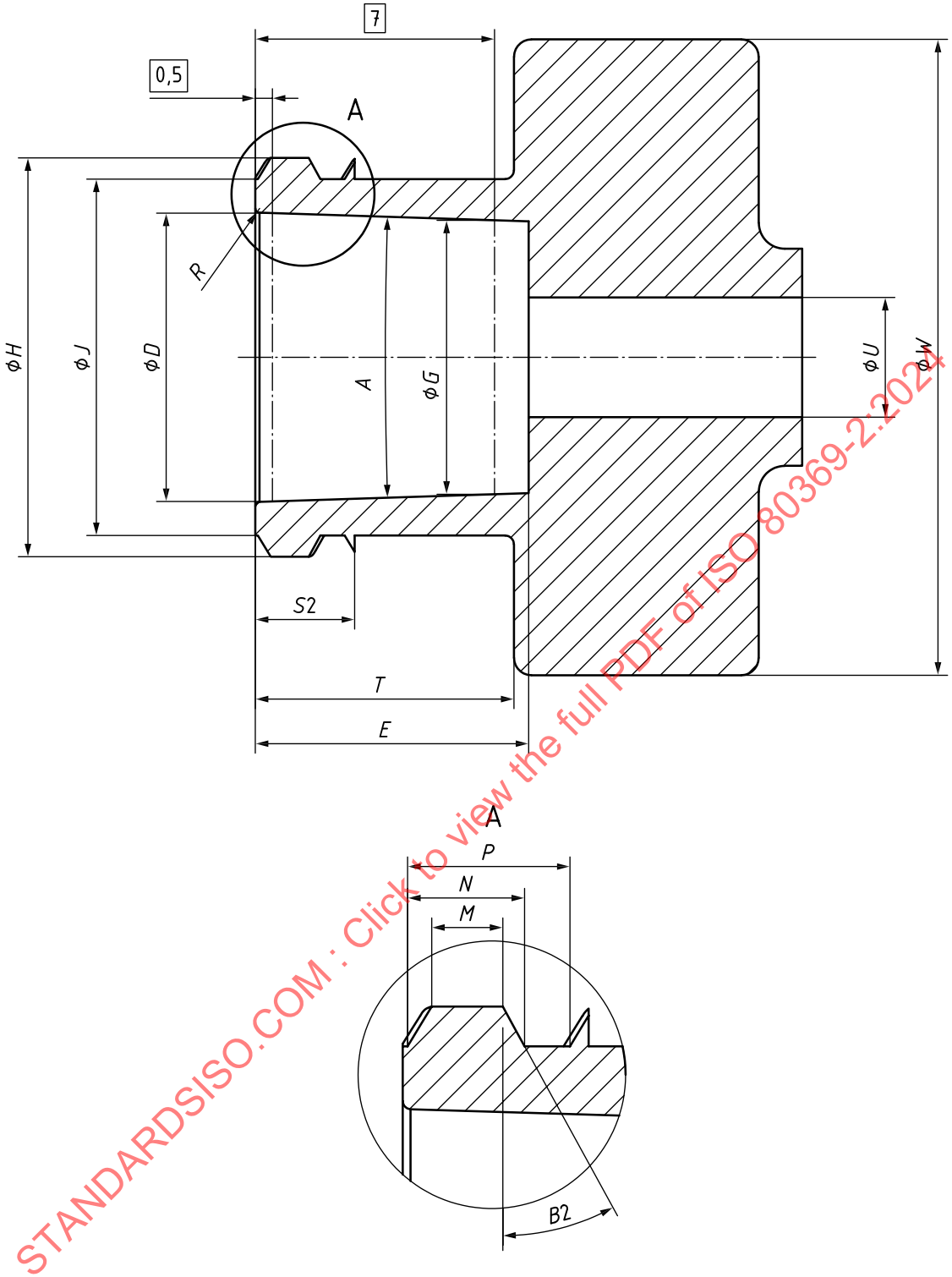


Figure B.4 — R2 *socket small-bore connectors*

Table B.4 — R2 *socket small-bore connector* dimensions

Dimensions in millimetres unless otherwise indicated

R2 *socket connector*				
Reference	**Designation**	**Dimension**		
		Minimum	***Nominal***	**Maximum**
A	Angle of taper, degrees (6 % taper *nominal*) (*auxiliary dimension*)	—	(3,437°)	—
B2	Angle of external thread profile on the bearing surface against separation, in degrees	27,5°	—	30,0°
ØD	Inside diameter at the open end of the *socket* taper at 0,500 (basic dimension) from the opening (large end) of the *socket* taper	8 385	—	8 487
E	Depth of *socket* taper	7 874	—	8 128
ØG	Inside diameter of the smaller end of the *socket* taper at 7,000 (basic dimension) from the opening (large end) of the *socket* taper	7 995		8 097
ØH	Outside major thread diameter of the *socket* lock *connector*, (diameter at thread crest)	11 543	—	11 797
ØJ	Minor inside thread diameter of the *socket* lock *connector*, (diameter at thread root)	10 301	—	10 555
M	Width of the thread form at the crest of a *socket* lock *connector*	1 082	—	1 142
N	Thread width of *socket* lock *connector* at root	1 799	—	1 859
P	*Nominal* pitch of double-start, right-hand thread of the *socket* lock *connector*	2 460		2620
R	Radius or chamfer at the entrance of the *socket* taper	0 000	—	0 250
S2	Thread length from open end of the *socket* taper	2 565	—	3 250
T	Distance from the *connector* face to the beginning of the grip geometry	7 569	—	—
ØU	Inner diameter of the fluid lumen	3 375	—	3 629
Øw	Diameter of the smallest cylinder that encompasses the outside surfaces of the external features of the collar [a]	18 340	—	18 872

[a] The minimum value of *w* shall be maintained for the length of 1,00 mm and the maximum value shall be maintained for the length of *E*.

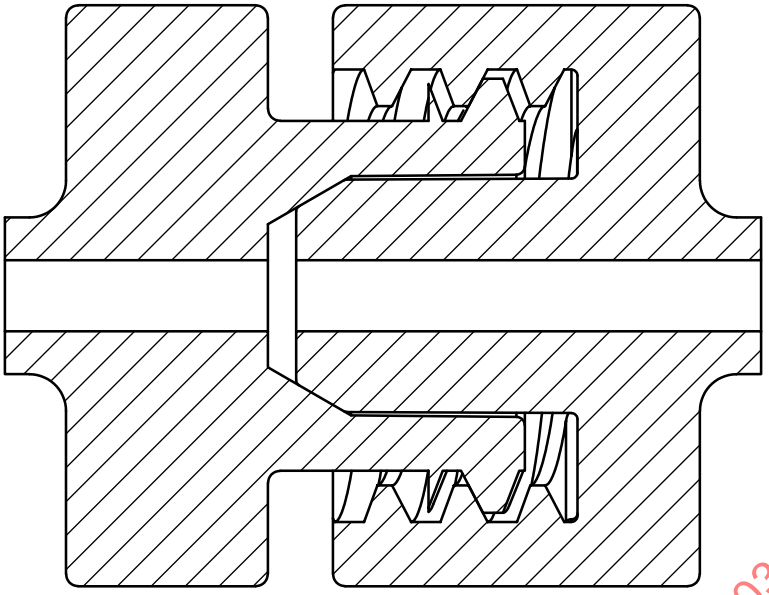


Figure B.5 — R1 *small-bore connector* assembly

Table B.5 contains the dimensions for Figure B.6.

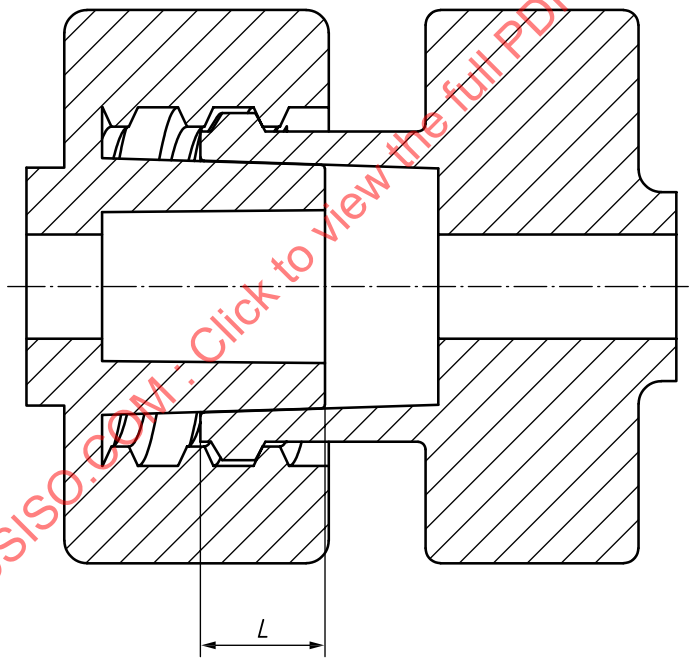


Figure B.6 — R2 *small-bore connector* assembly

Table B.5 — R2 *small-bore connector* assembly

Dimensions in millimetres unless otherwise indicated

R2 *connector* assembly				
Reference	**Designation**	**Dimension**		
		Minimum	***Nominal***	**Maximum**
L	Length of engagement (*auxiliary dimensions*) (see Figure B.5)	—	(4 188) (4 683)	—

Annex C
(normative)

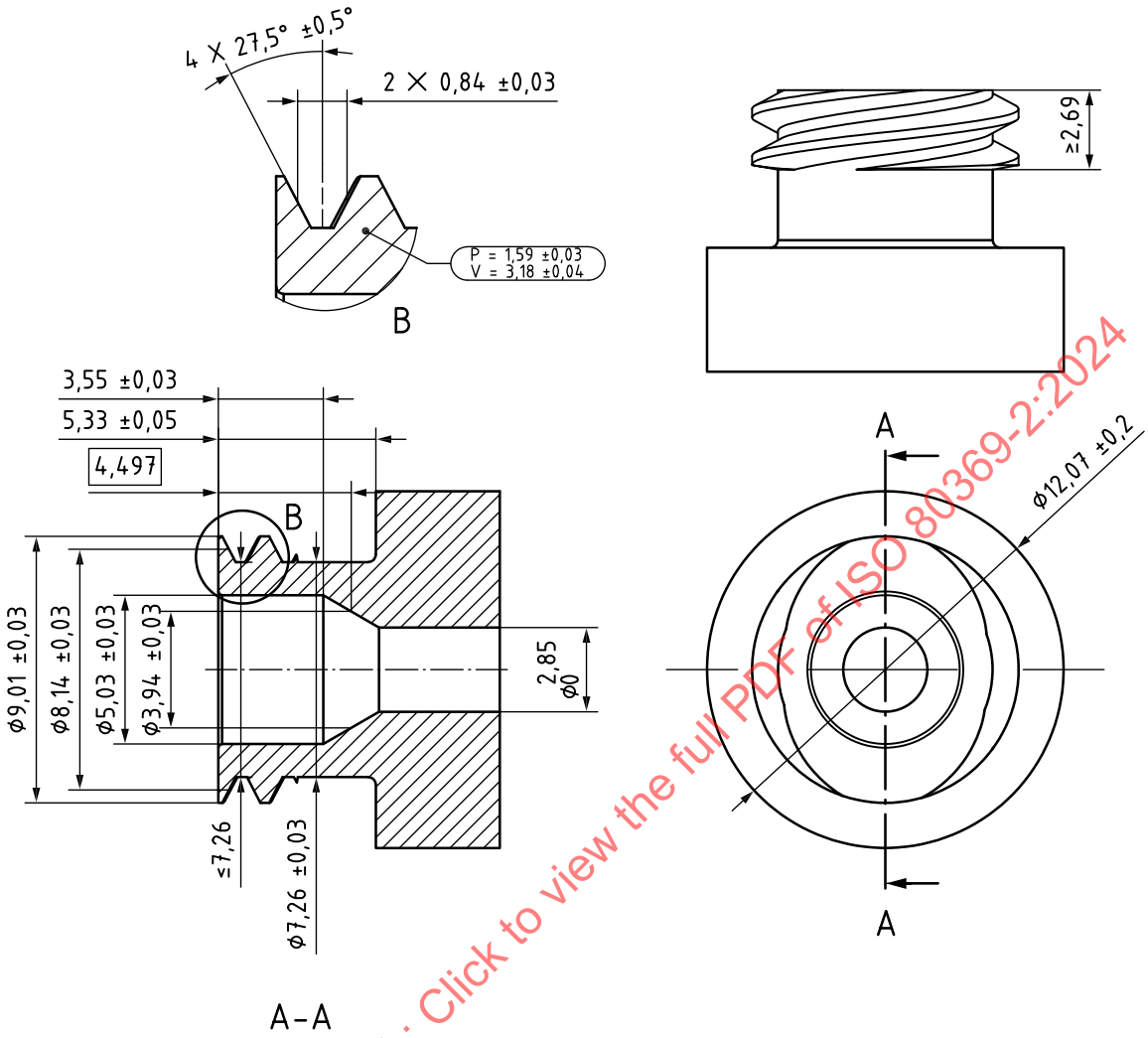
Reference *connectors* for testing *small-bore connectors* for *respiratory applications*

C.1 General requirements for reference *connectors*

The reference *connectors* shall be manufactured from corrosion-resistant *rigid materials* with a modulus of elasticity either in flexure or in tension greater than 35 000 kg/cm^2 (3 433 MPa) and with a surface roughness value, R_a, not exceeding 0,8 µm on critical surfaces. See Figures C.1 to C.14.

C.2 Reference *connectors* for R1 *small-bore connectors*

Dimensions in millimetres



Key

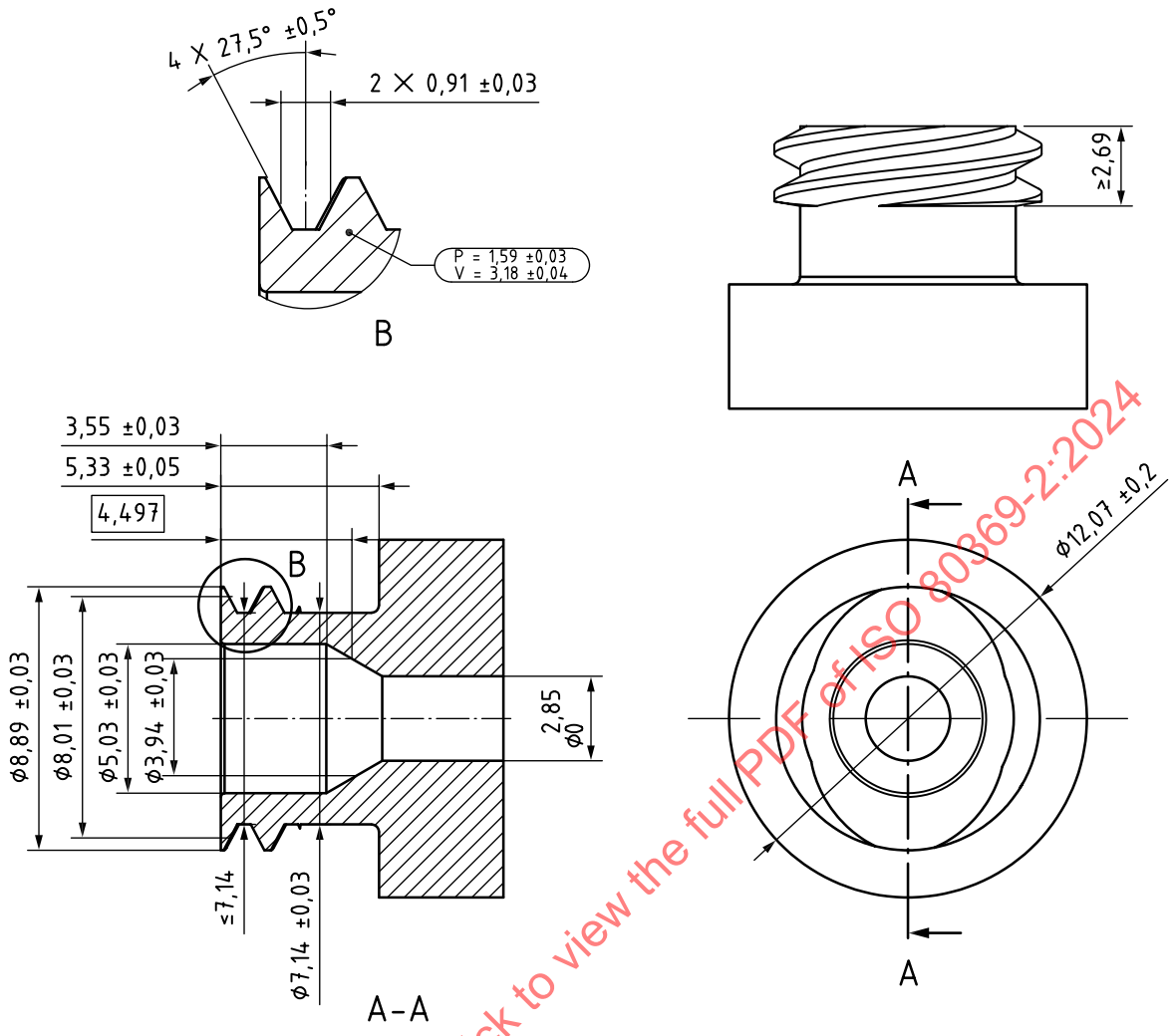
P thread pitch

V thread lead for a double start thread

All sharp edges and corners shall have a radius no greater than 0,15 mm (unless otherwise specified) for manufacturing purposes.

Figure C.1 — *Socket* reference *connector* for testing R1 *cone connectors* for leakage, separation from unscrewing, stress cracking and *non-interconnectable* characteristics

Dimensions in millimetres



Key

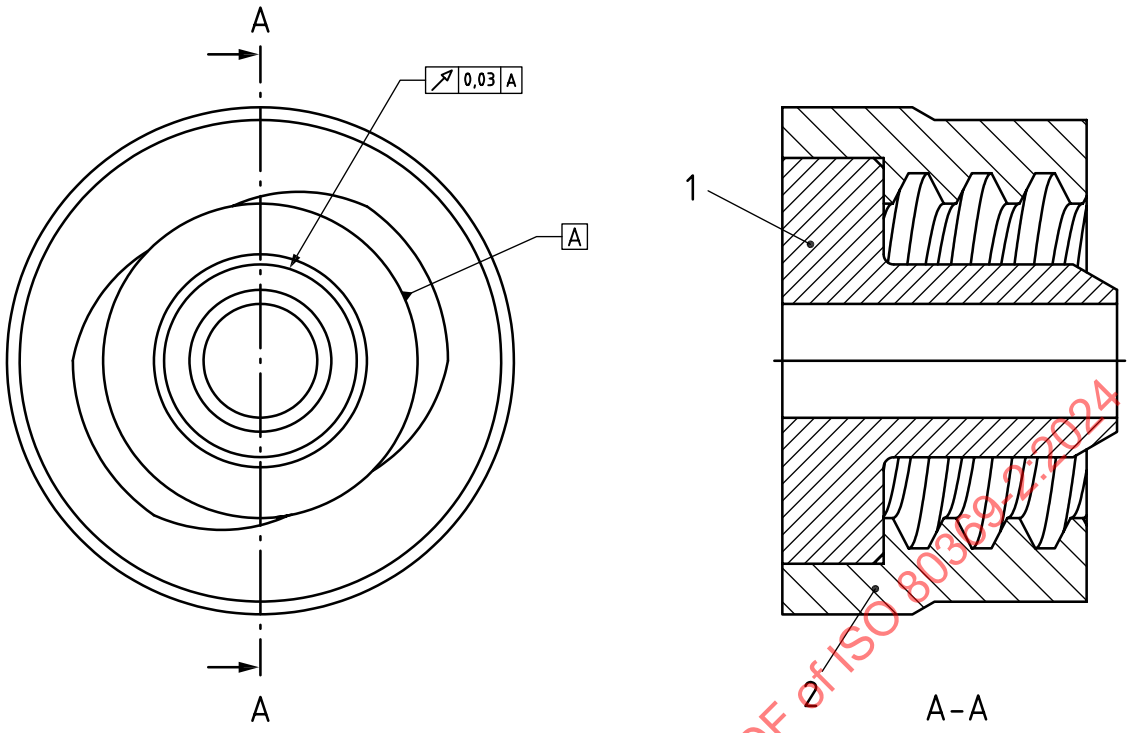
P thread pitch

V thread lead for a double start thread

All sharp edges and corners of lug shall have a radius no greater than 0,15 mm (unless otherwise specified) for manufacturing purposes.

Figure C.2 — *Socket* reference *connector* for testing R1 *cone connectors* for separation from axial load and resistance to overriding

Dimensions in millimetres



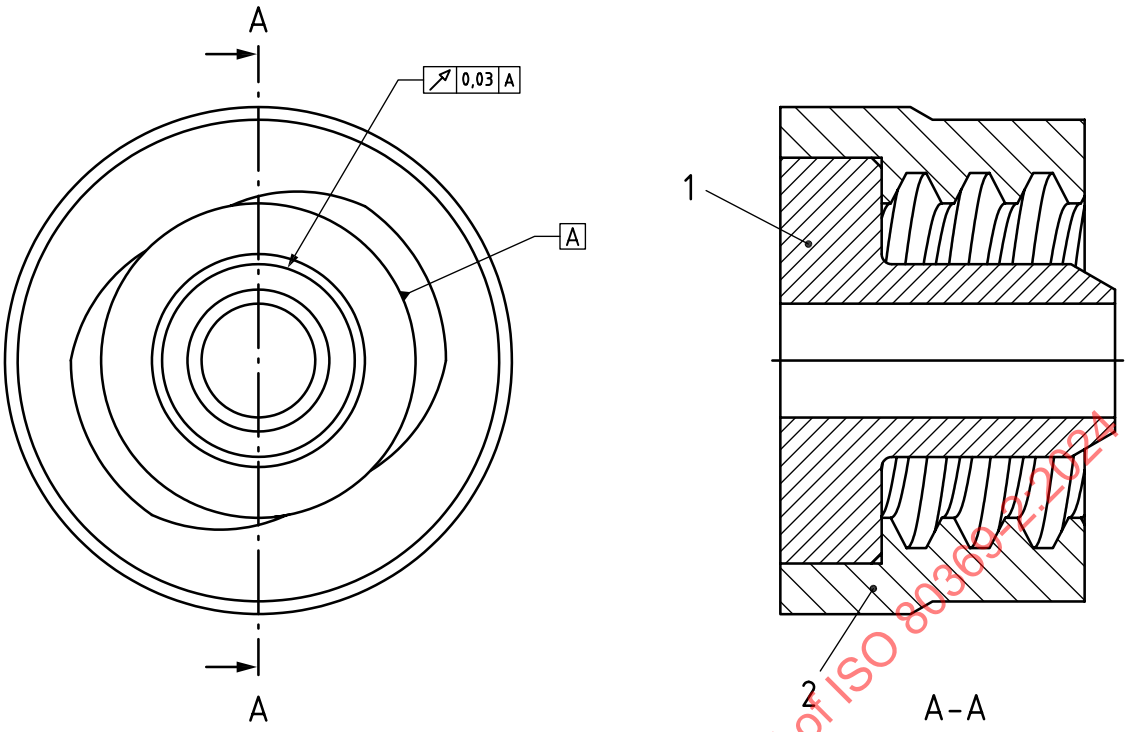
Key

1 R1 *cone* taper insert

2 R1 *cone* reference *connector*

Create this *cone* reference *connector* assembly by attaching the *cone* taper insert (Figure C.5) to the reference *connector* (Figure C.6).

Figure C.3 — *Cone* reference *connector* for testing R1 *socket connectors* for leakage, separation from unscrewing, stress cracking and *non-interconnectable* characteristics



Key

1 R1 *cone* taper insert

2 R1 *cone* reference *connector*

Create this *cone* reference *connector* assembly by attaching the *cone* taper insert (Figure C.5) to the reference *connector* (Figure C.7).

Figure C.4 — *Cone* reference *connector* for testing R1 *socket connectors* from separation from axial load and resistance to overriding

C.3 Reference *connector* components for R1 *small-bore connectors*

Dimensions in millimetres

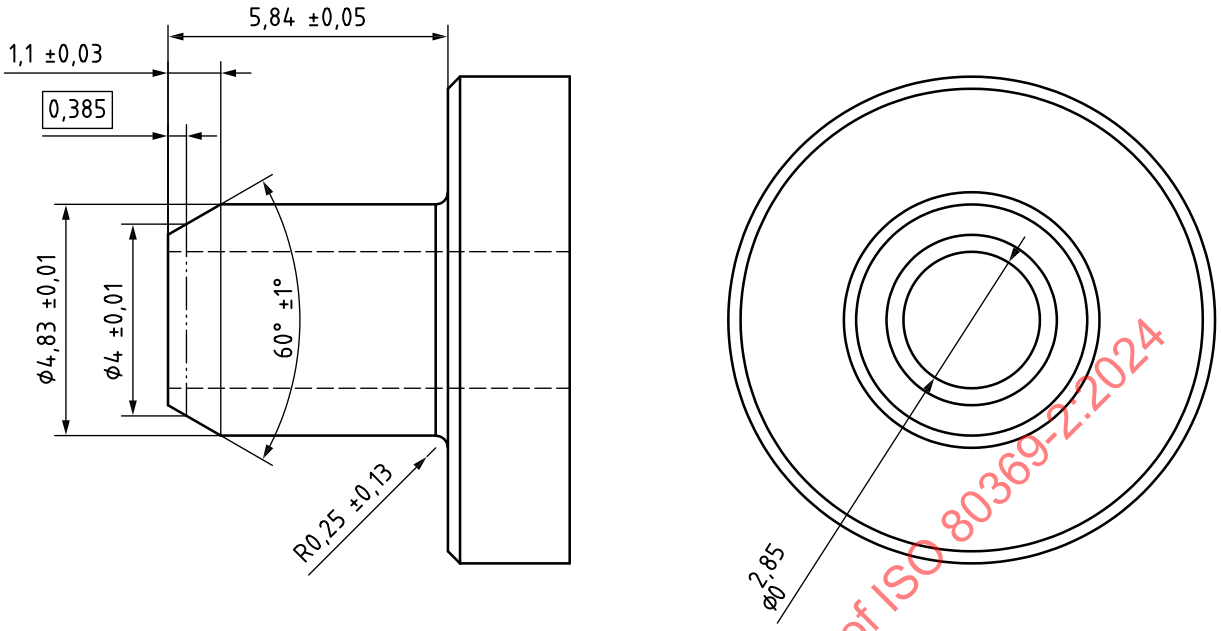
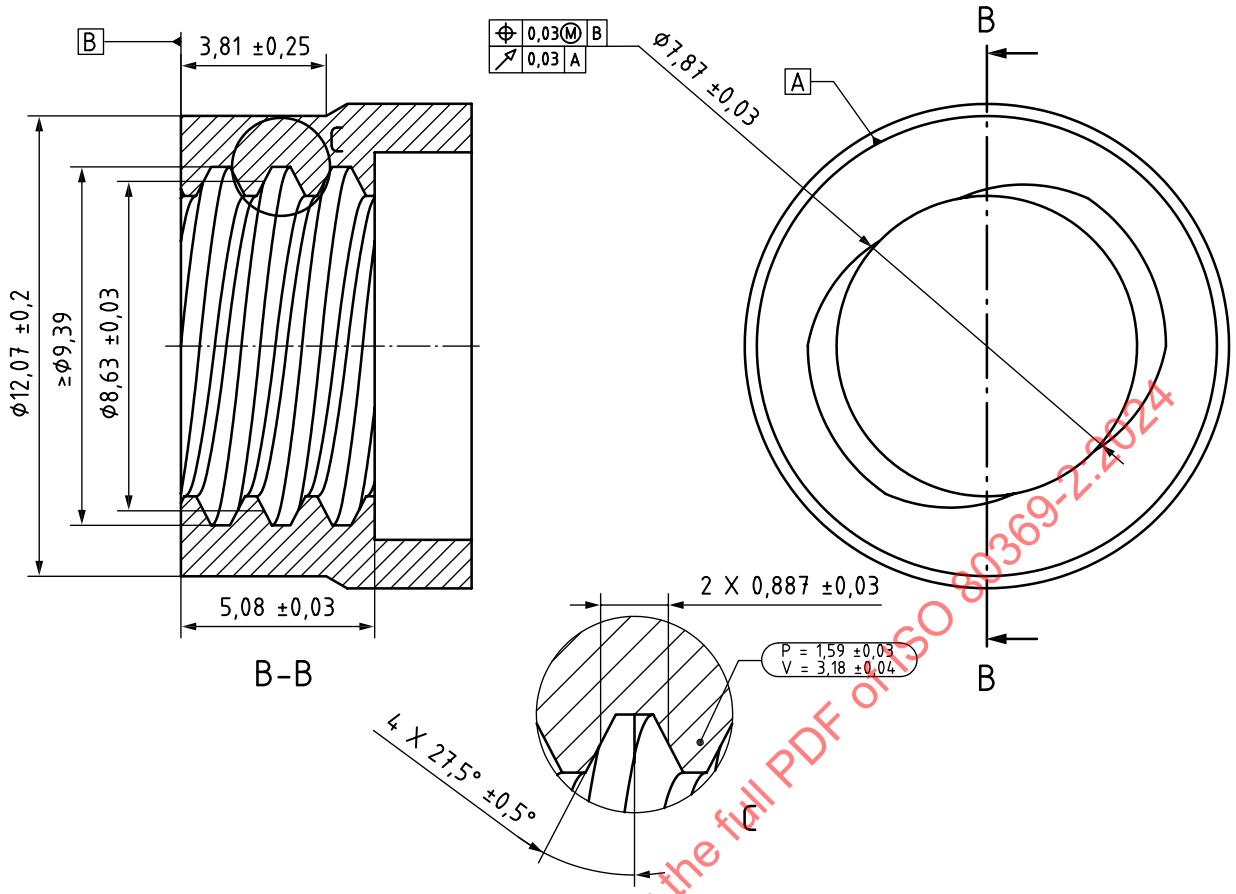


Figure C.5 — *Cone* reference *connector cone* taper insert for testing R1 *socket connectors* for leakage, separation from unscrewing, separation from axial load and resistance to overriding, stress cracking and *non-interconnectable* characteristics

Dimensions in millimetres



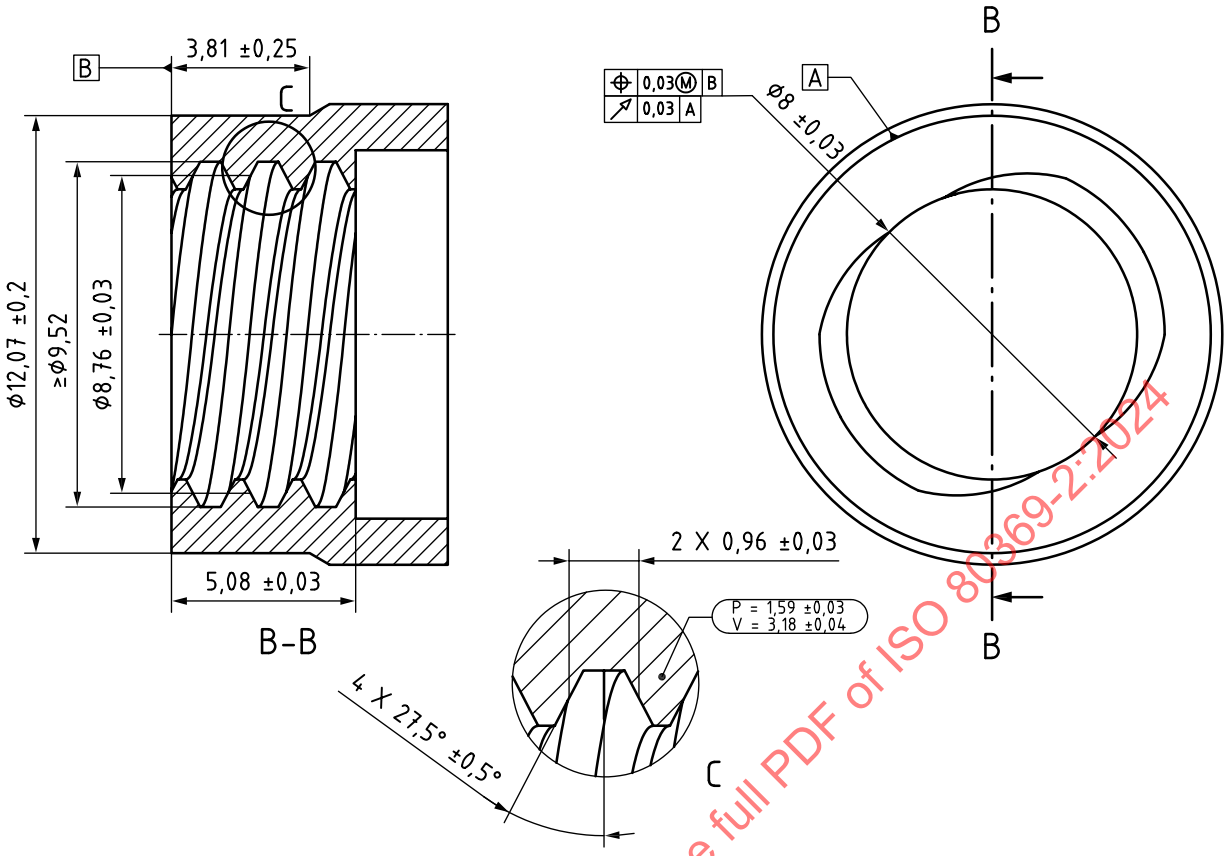
Key

P thread pitch

V thread lead for a double start thread

Figure C.6 — *Cone* reference *connector* for testing R1 *socket connectors* for leakage, separation from unscrewing, stress cracking and *non-interconnectable* characteristics

Dimensions in millimetres



Key

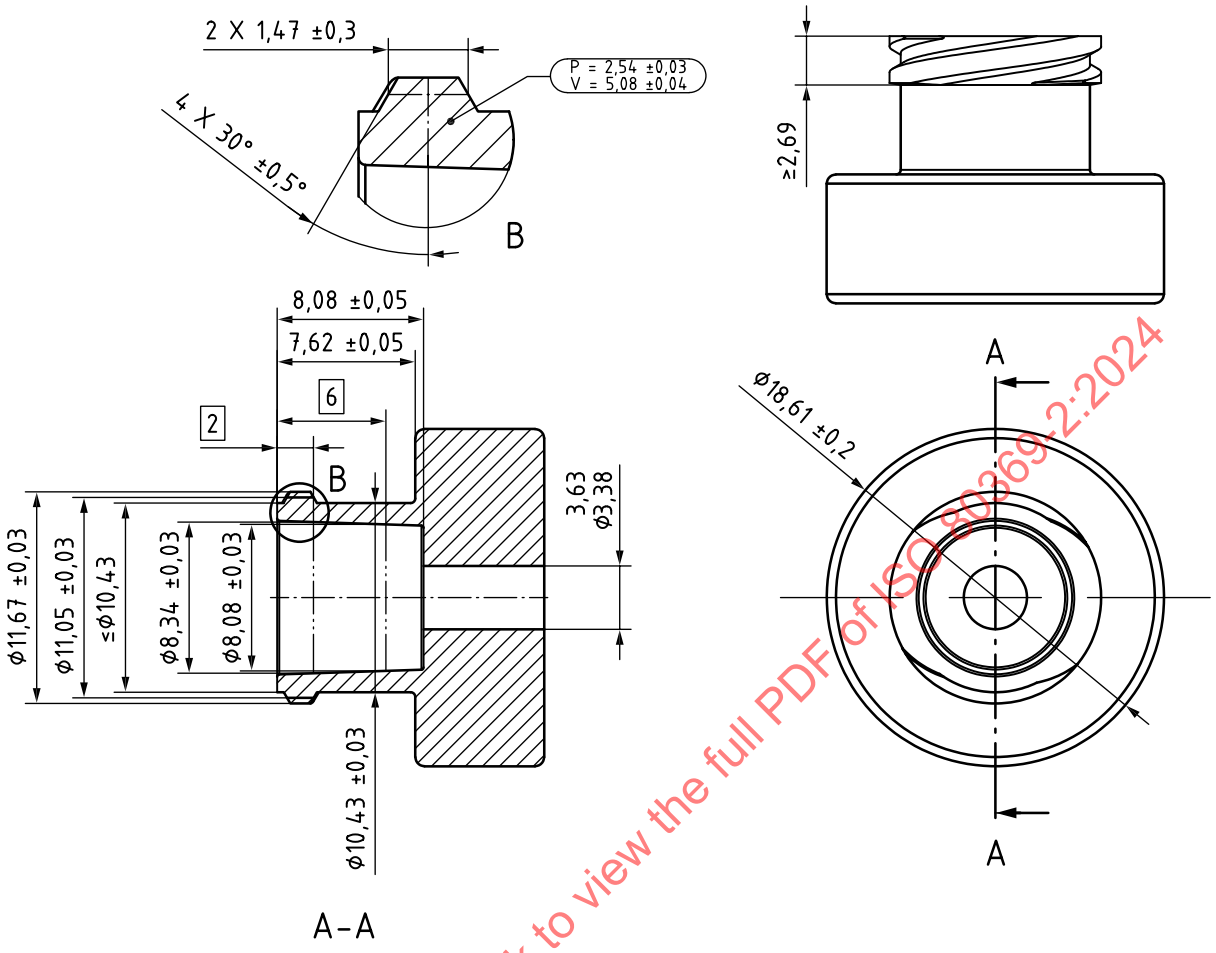
P thread pitch

V thread lead for a double start thread

Figure C.7 — *Cone* reference *connector* for testing R1 *socket connectors* separation from axial load and resistance to overriding

C.4 Reference *connectors* for R2 *small-bore connectors*

Dimensions in millimetres



Key

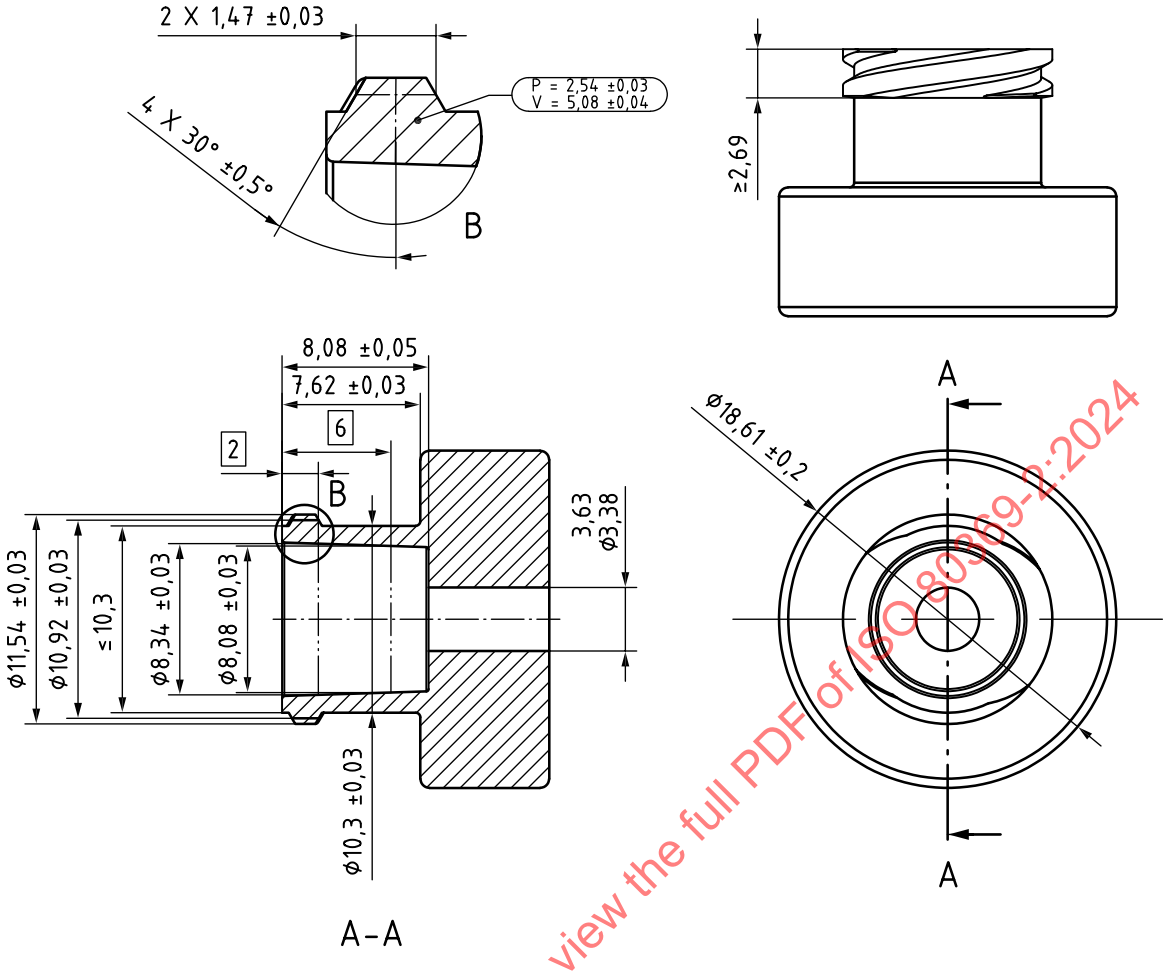
P thread pitch

V thread lead for a double start thread

All sharp edges and corners of thread form shall have a radius no greater than 0,15 mm (unless otherwise specified) for manufacturing purposes.

Figure C.8 — *Socket* reference *lock connector* for testing R2 *cone connectors* for leakage, separation from unscrewing, stress cracking and *non-interconnectable* characteristics

Dimensions in millimetres



Key

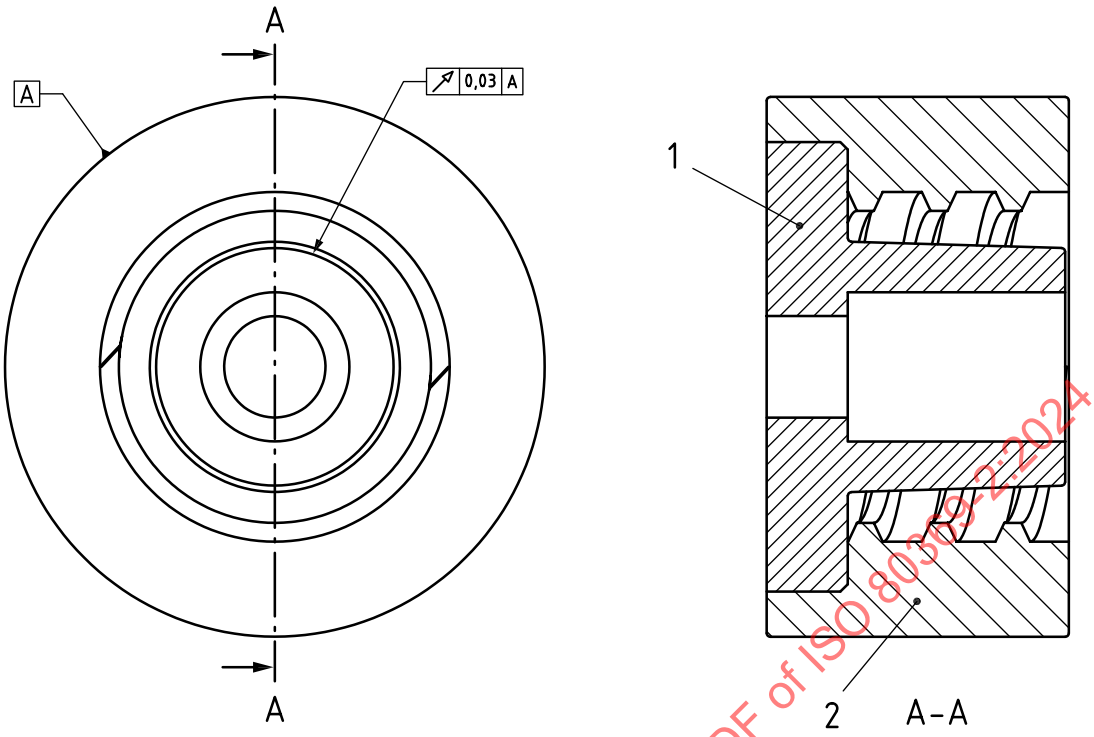
P thread pitch

V thread lead for a double start thread

All sharp edges and corners of lug shall have a radius of greater than 0,15 mm (unless otherwise specified) for manufacturing purposes.

Figure C.9 — *Socket* reference *connector* for testing R2 *cone connectors* for separation from axial load and resistance to overriding

Dimensions in millimetres



Key

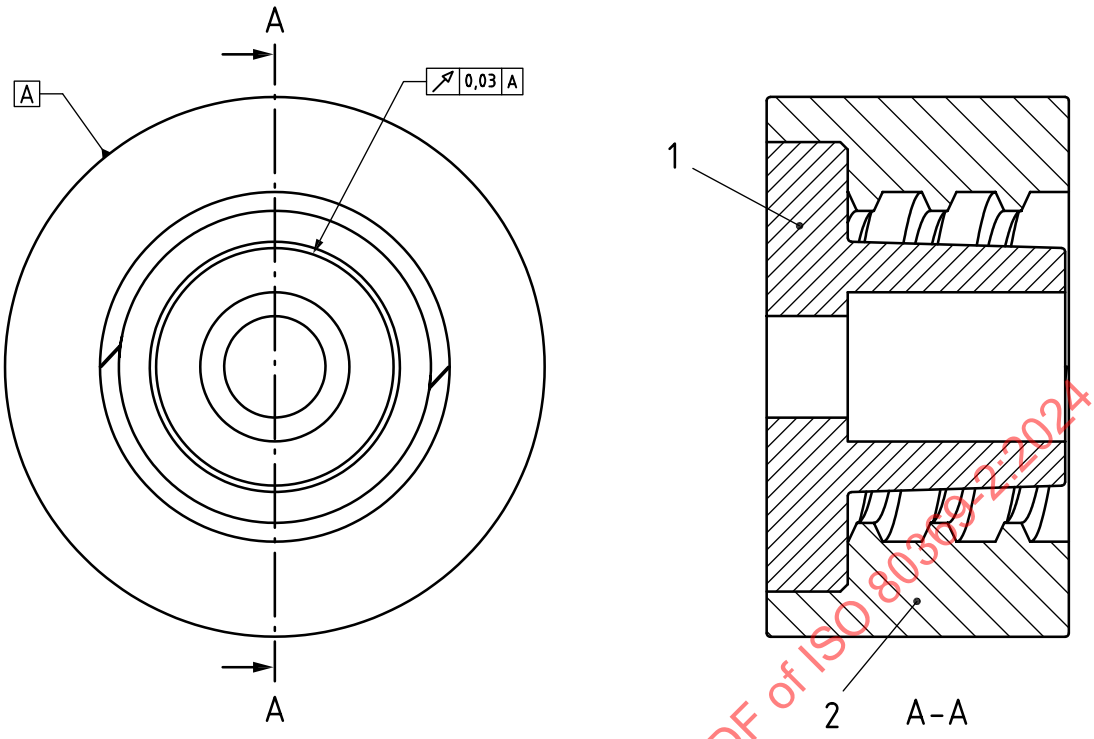
1 R2 *cone* taper insert

2 R2 *cone* reference *connector*

Create this *cone* reference *connector* assembly by attaching the *cone* taper insert (Figure C.12) to the reference *connector* (Figure C.13).

Figure C.10 — *Cone* reference *lock connector* for testing R2 *socket connectors* for leakage, separation from unscrewing, stress cracking and *non-interconnectable* characteristics

Dimensions in millimetres



Key

1 R2 *cone* taper insert

2 R2 *cone* reference *connector*

Create this *cone* reference *connector* assembly by attaching the *cone* taper insert (Figure C.12) to the reference *connector* (Figure C.14).

Figure C.11 — *Cone* reference *connector* for testing R2 *socket connectors* separation from axial load and resistance to overriding

C.5 Reference *connector* components for R2 *small-bore connectors*

Dimensions in millimetres

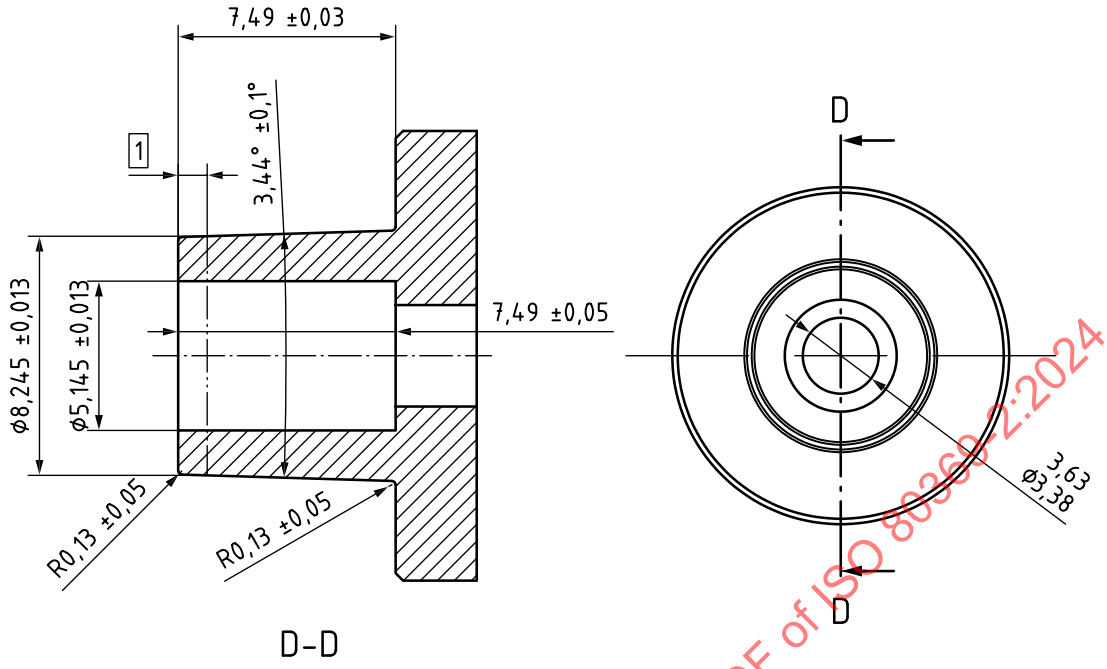
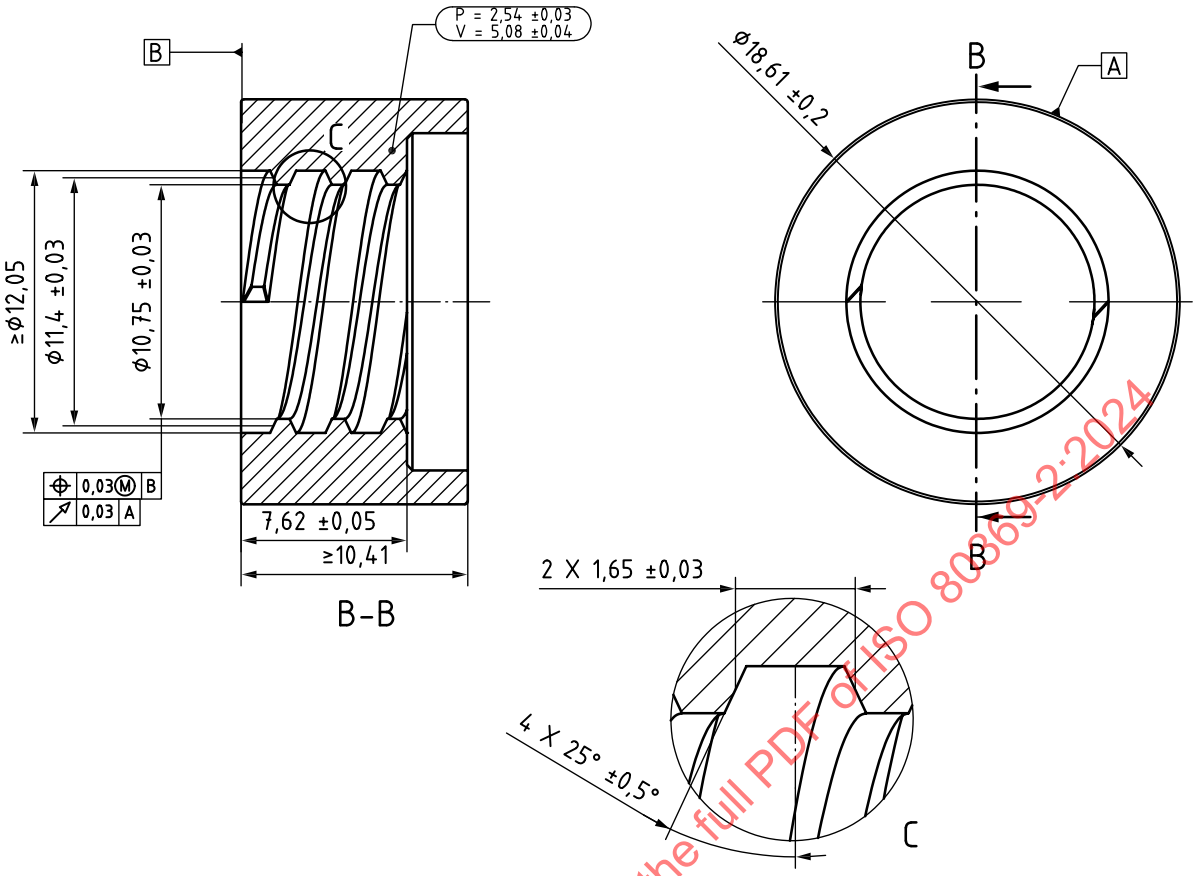


Figure C.12 — *Cone* reference *connector cone* taper insert for testing R2 *socket connectors* for leakage, separation from unscrewing, stress cracking and separation from axial load and resistance to overriding

Dimensions in millimetres



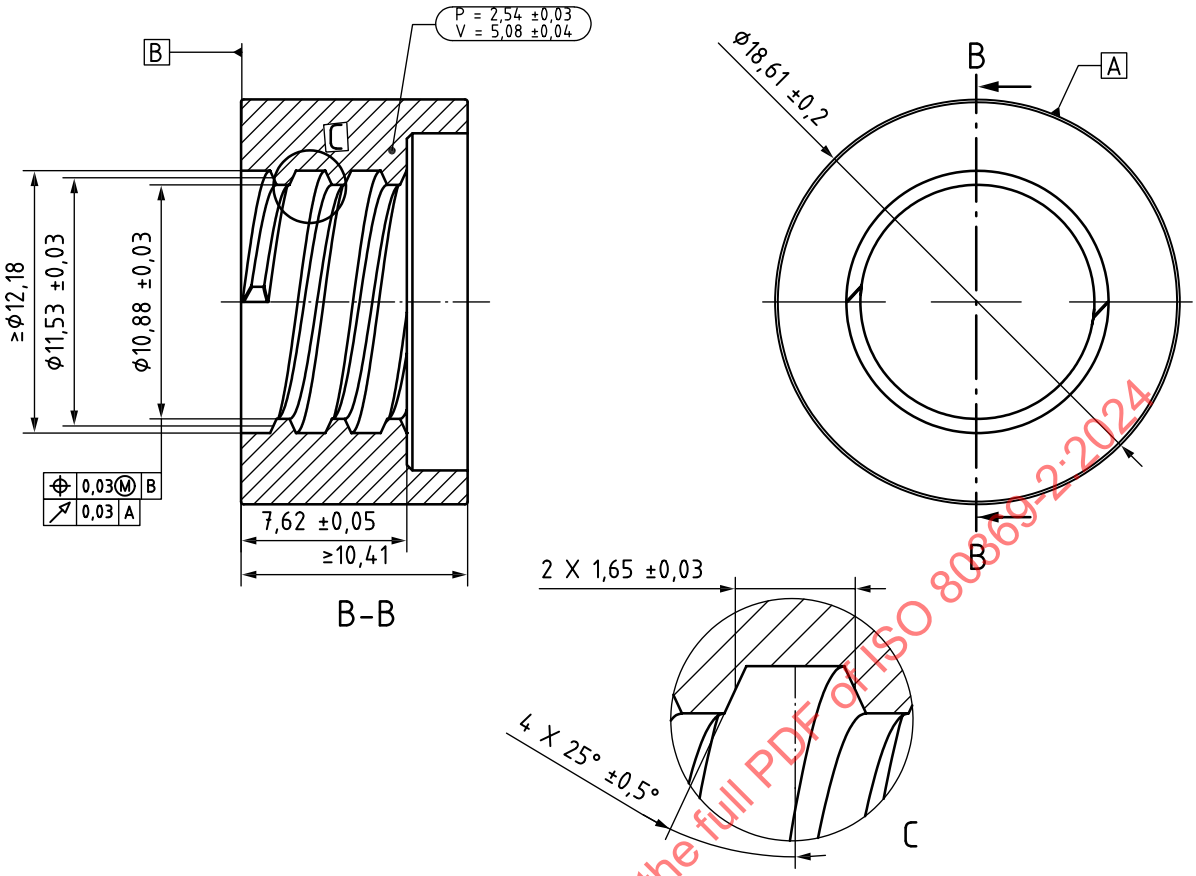
Key

P thread pitch

V thread lead for a double start thread

Figure C.13 — *Cone* reference *connector* for testing R2 *socket connectors* for leakage, separation from unscrewing, stress cracking and *non-interconnectable* characteristics

Dimensions in millimetres



Key

P thread pitch

V thread lead for a double start thread

Figure C.14 — *Cone* reference *connector* for testing R2 *socket connectors* separation from axial load and resistance to overriding

Annex D
(informative)

Assessment of *medical devices* and their attributeswith *connections* within this *application*

Table D.1 contains examples of *medical devices* and *accessories* with *connections* to the ancillary port *connection* of a *breathing system* or to be used with a respirable gas. The table contains an assessment of the important attributes of *medical devices* and *accessories* as they relate to the intended *connection*. Each *connection* is assessed according to the following index or subgroups:

a) *breathing system connections;*

b) diverting gas monitor *connections*;

c) oxygen source *connections;*

d) oxygen saving systems *connections;*

e) humidifier system *connections;*

f) sub-atmospheric *connections;*

g) *connections* for the delivery of liquids or drugs.

Table D.1 — Examples of *medical devices* with *connections* within this *application* and their attributes

Part /component to which the *connector* is applied	Index / Sub-group	Maximum pressure A: < 150 hPa B: > 150 hPa	A: Air B: Oxygen	Control *risk* of Barotrau-mas	Control *risk* of hypoxia	Type of fluid adminis-tered	Pressure range hPa	Flow range l/min	Dynamic sig-nal to pass through	Locking means neces-sary	Syringe needed
Outlet port on a *breath-ing system* to connect a breathing pressure sensor	1.1.1	A	—	yes	yes	gas	< 125	< 0,05	yes	yes	no
Inlet port of a breathing pressure measuring line to connect to the *breathing system*	1.1.2	A	—	yes	yes	gas	< 125	< 0,05	yes	yes	no
Outlet port of a breathing pressure measuring line to connect to the pressure sensor	1.1.3	A	—	yes	yes	gas	< 125	< 0,05	yes	yes	no
Inlet port on the pressure sensor (e.g. ventilator) to connect the outlet port of a breathing pressure measuring line	1.1.4	A	—	yes	yes	gas	< 125	< 0,05	yes	yes	no

Key

Port is intended to mean any opening in the part of the *medical device* or the *accessory* concerned, including those with a *connector* as well as those without a *connector*.

[a] *Connections* for this use are typically designed to fit the specific aerosolized drug container.

[b] This port typically has a rigid attachment component and an elastomeric port.

Table D.1 *(continued)*

Part /component to which the *connector* is applied	Index / Sub-group	Maximum pressure A: < 150 hPa B: > 150 hPa	A: Air B: Oxygen	Control *risk* of Barotrau-mas	Control *risk* of hypoxia	Type of fluid adminis-tered	Pressure range hPa	Flow range l/min	Dynamic sig-nal to pass through	Locking means neces-sary	Syringe needed
Port on a *breathing system* to connect a fluid sam-pling line	1.2.1	A	—	yes	yes	liquid	− 800 to 125	10 ml in 3 s	no	no	yes
Inlet port of a fluid sam-pling line to connect to the *breathing system*	1.2.2	A	—	yes	yes	liquid	− 800 to 125	10 ml in 3 s	no	no	yes
Outlet port of a fluid sam-pling line to connect to the fluid sampler	1.2.3	A	—	yes	yes	liquid	− 800 to 125	10 ml in 3 s	no	no	yes
Inlet port on a fluid sam-pler system to connect to the outlet port of a fluid sampling line	1.2.4	A	—	no	no	liquid	− 800 to 0	10 ml in 3 s	no	no	no
Inlet port on an expiratory valve within the *breathing system* to connect the line which controls the valve	1.3.1	A	—	no	no	gas	< 125	3 ml in 0,1 s	yes	yes	no
Outlet port on the con-necting line to be connect-ed to the expiratory valve	1.3.2	A	—	no	no	gas	< 125	3 ml in 0,1 s	yes	yes	no
Inlet port on the connect-ing line to the expiratory valve to be connected to the ventilator	1.3.3	A	—	no	no	gas	< 125	3 ml in 0,1 s	yes	yes	no
Outlet port on the ventila-tor to connect the connect-ing line to the expiratory valve	1.3.4	A	—	no	no	gas	< 125	3 ml in 0,1 s	yes	yes	no
Driving gas inlet port on a nebuliser integral to the *breathing system*	1.4.1	B	—	yes	yes	gas	< 1 000	< 125	no	yes	no
Outlet port on a nebu-liser driving gas line to connect to the driving gas inlet port on an integral nebuliser	1.4.2	B	—	yes	yes	gas	< 1 000	< 15	no	yes	no
Inlet port on a nebuliser driving gas line to connect to the driving gas outlet of the driving gas source	1.4.3	B	—	yes	yes	gas	< 1 000	< 15	no	yes	no
Driving gas outlet port of the driving gas source to connect to the inlet port on a nebuliser driving gas line	1.4.4	B	A, B	yes	yes	gas	< 1 000	< 15	no	yes	no

Key

Port is intended to mean any opening in the part of the *medical device* or the *accessory* concerned, including those with a *connector* as well as those without a *connector*.

[a] *Connections* for this use are typically designed to fit the specific aerosolized drug container.

[b] This port typically has a rigid attachment component and an elastomeric port.

Table D.1 *(continued)*

Part /component to which the *connector* is applied	Index / Sub-group	Maximum pressure A: < 150 hPa B: > 150 hPa	A: Air B: Oxygen	Control *risk* of Barotraumas	Control *risk* of hypoxia	Type of fluid administered	Pressure range hPa	Flow range l/min	Dynamic signal to pass through	Locking means necessary	Syringe needed
Inlet port on a *breathing system* for the emergency administration of drugs	1.5.1	A	—	yes	yes	liquid	< 125	10 ml in 3 s	no	no	yes
Nebuliser outlet port for drug administration into the *breathing system*	1.5.2	B	—	yes	yes	liquid	< 125	10 ml in 3 s	no	no	yes
Port on a *breathing system* to connect a meter dose inhaler (MDI)[a]	1.5.3	A	—	yes	yes	gas / liquid	< 125	10 ml in 3 s	no	no	yes
Inlet port on a *breathing system* for the administration of liquid for the irrigation of *patient's* airway	1.6.0	A	—	yes	yes	liquid	< 125	10 ml in 3 s	no	no	yes
Port to insert a heated wire into the breathing tube	1.7.0	A	—	yes	yes	n/a	< 125	< 0,01	no	yes	no
Port to insert a temperature sensor into a *breathing system*	1.8.0	A	—	yes	yes	n/a	< 125	0	n/a	n/a	n/a
Port on a *breathing system* to connect a gas monitor sampling line	2.1.1	A	—	yes	yes	gas	– 400 to 125	0,02 to 0,5	yes	yes	no
Inlet port of a gas monitor sampling line to connect to the *breathing system*	2.1.2	A	—	yes	yes	gas	– 400 to 125	0,02 to 0,5	yes	yes	no
Outlet port of a gas monitor sampling line to connect to a diverting respiratory gas monitor	2.1.3	A	—	yes	yes	gas	– 400 to 125	0,02 to 0,5	yes	yes	no
Input port on a diverting respiratory gas monitor	2.1.4	A	—	yes	yes	gas	– 400 to 125	0,02 to 0,5	no	yes	no
Input port on a water trap of a diverting respiratory gas monitor	2.2	A	—	yes	yes	gas	– 400 to 125	0,02 to 0,5	no	yes	no
Input port of a filter used on the inlet port of a diverting respiratory gas monitor	2.3	A	—	yes	yes	gas	– 400 to 125	0,02 to 0,5	no	yes	no
Return (output) port on a diverting respiratory gas monitor	2.4.1	A	—	yes	yes	gas	< 125	0,02 to 0,5	no	yes	no

Key

Port is intended to mean any opening in the part of the *medical device* or the *accessory* concerned, including those with a *connector* as well as those without a *connector*.

[a] *Connections* for this use are typically designed to fit the specific aerosolized drug container.

[b] This port typically has a rigid attachment component and an elastomeric port.

Table D.1 *(continued)*

Part /component to which the *connector* is applied	Index / Sub-group	Maximum pressure A: < 150 hPa B: > 150 hPa	A: Air B: Oxygen	Control *risk* of Barotrau-mas	Control *risk* of hypoxia	Type of fluid adminis-tered	Pressure range hPa	Flow range l/min	Dynamic sig-nal to pass through	Locking means neces-sary	Syringe needed
Inlet port of a gas monitor return line to connect to the return port of a diverting respiratory gas monitor	2.4.2	A	—	yes	yes	gas	< 125	0,02 to 0,5	no	yes	no
Outlet port of a gas moni-tor return line to connect to the *breathing system* return port	2.4.3	A	—	yes	yes	gas	< 125	0,02 to 0,5	no	yes	no
Return (inlet) port on the *breathing system* to connect to the gas monitor gas return line	2.4.4	A	—	yes	yes	gas	< 125	0,02 to 0,5	no	yes	no
Exhaust port on a di-verting respiratory gas monitor	2.5.0	A	—	yes	yes	gas	- 400 to 125	0,05 to 0,5	no	yes	no
Water outlet port on a water trap used on the input port of a diverting respiratory gas monitor	2.6.0	A	—	yes	yes	liquid	< 125	< 1	no	yes	no
Output port of a gaseous oxygen delivery source	4.1.1	B	B	no	yes	gas	< 6 000	< 30	no	yes	no
Inlet port of a *patient* oxygen delivery line to connect to a gaseous oxy-gen delivery source	4.1.2	B	B	no	yes	gas	< 6 000	< 30	no	yes	no
Outlet port of a *patient* oxygen delivery line to connect to the input port of various masks, prongs etc.	4.1.3	B	B	no	yes	gas	< 6 000	< 30	no	yes	no
Gas input port of various masks, prongs, breathing set (e.g. tubing as in ISO 5367), etc.	4.1.4	A	B	yes	yes	gas	< 125	< 15	yes	yes	no
Output port of an oxygen concentrator	4.2.0	B	B	yes	yes	gas	< 1 000	< 15	no	no	no
Output port of liquid oxy-gen system	4.3.0	B	B	yes	yes	gas	< 200	< 15	no	no	no
Output port of an oxygen flow meter	4.4.0	B	B	no	yes	gas	< 6 000	< 20	no	yes	no
Input port of an oxygen conserving (saving) device	5.1.1	B	B	no	yes	gas	< 6 000	< 20	no	yes	no

Key

Port is intended to mean any opening in the part of the *medical device* or the *accessory* concerned, including those with a *connector* as well as those without a *connector*.

[a] *Connections* for this use are typically designed to fit the specific aerosolized drug container.

[b] This port typically has a rigid attachment component and an elastomeric port.

Table D.1 *(continued)*

Part /component to which the *connector* is applied	Index / Sub-group	Maximum pressure A: < 150 hPa B: > 150 hPa	A: Air B: Oxygen	Control *risk* of Barotrau-mas	Control *risk* of hypoxia	Type of fluid adminis-tered	Pressure range hPa	Flow range l/min	Dynamic sig-nal to pass through	Locking means neces-sary	Syringe needed
Outlet port of an oxygen delivery line to connect to the input port of an oxy-gen conserving (saving) device	5.1.2	B	B	no	yes	gas	< 6 000	< 20	no	yes	no
Inlet port of an oxygen delivery line to connect to gaseous oxygen delivery source	5.1.3	B	B	no	yes	gas	< 6 000	< 20	no	yes	no
Output port of an oxygen conserving (saving) device	5.2.0	A	B	yes	yes	gas	< 125	< 15	yes	no	no
Inlet port of a venturi mask system	5.3.0	B	A, B	no	yes	gas	< 6 000	< 20	no	yes	no
Water filling (inlet) port on a heated humidifier	6.1.1	A	—	yes	yes	liquid	< 125	0,2	no	yes	yes
Outlet port of the tubing set to connect to the filling port on a heated humidifi-er (for filling the humidi-fier)	6.1.2	A	—	no	yes	liquid	< 100	1	no	yes	no
Spike (inlet port) on the tubing set for filling the humidifier	6.1.3	A	—	no	no	liquid	< 100	1	no	n/a	no
Bag (outlet) port to con-nect the tubing set for filling the humidifier	6.1.4	A	—	no	no	liquid	< 100	1	no	yes	no
Water administration port on a heat and moisture exchanger (HME)	6.2.1	A	—	yes	yes	liquid	< 125	< 0,001	no	yes	yes
Outlet port of the water supply line to connect to the water inlet port on a HME	6.2.2	B	—	yes	yes	liquid	< 125	< 0,001	no	yes	yes
Inlet port of the water supply line to connect to the water supply	6.2.3	A	—	yes	yes	liquid	< 125	< 0,001	no	yes	yes
Outlet port of the water supply to connect to the water supply line	6.2.4	A	—	yes	yes	liquid	< 125	< 0,001	no	yes	yes
Closed suctioning port on the *breathing system* for introducing the suction catheter [b]	8.2.0	A	—	yes	yes	n/a	< 125	0	n/a	n/a	n/a

Key

Port is intended to mean any opening in the part of the *medical device* or the *accessory* concerned, including those with a *connector* as well as those without a *connector*.

[a] *Connections* for this use are typically designed to fit the specific aerosolized drug container.

[b] This port typically has a rigid attachment component and an elastomeric port.

Table D.1 *(continued)*

Part /component to which the *connector* is applied	Index / Sub-group	Maximum pressure A: < 150 hPa B: > 150 hPa	A: Air B: Oxygen	Control *risk* of Barotrau-mas	Control *risk* of hypoxia	Type of fluid adminis-tered	Pressure range hPa	Flow range l/min	Dynamic sig-nal to pass through	Locking means neces-sary	Syringe needed
Port on a *breathing system* to administer a liquid to irrigate *patient's* airway	9.1.0	A	—	yes	yes	liquid	< 125	10 ml in 3 s	no	no	no
Port on a *breathing system* for drug delivery prior to intubation	9.2.0	A	—	no	no	liquid	< 125	10 ml in 3 s	no	no	Yes

Key

Port is intended to mean any opening in the part of the *medical device* or the *accessory* concerned, including those with a *connector* as well as those without a *connector*.

[a] *Connections* for this use are typically designed to fit the specific aerosolized drug container.

[b] This port typically has a rigid attachment component and an elastomeric port.

Annex E
(informative)

Summary of the usability requirements for *small-bore connectors* for *respiratory applications*

E.1 *User profile*

The *user profile* is a summary of the mental, physical and demographic traits of an intended *user* population, as well as any special characteristics that can have a bearing on design decisions, such as occupational skills and job requirements.

E.2 Use scenarios

Use scenarios for *small-bore connectors* for respiratory *applications* can differ by *user* group, and are comprised of the multitude of sub-*applications* of the *connectors* within different sub-specialities.

E.3 Use environments

E.3.1 Facilities

Facilities are hospitals, office-based medical services, home care, transport medical services, emergency care and other facilities in which gas outlets of medical gases are used to connect to *medical devices* for *patient* use.

E.3.2 Use temperatures

The following temperature environment is expected for respiratory *small-bore connectors*: ambient temperature, −40 °C to +60 °C (for field use in emergency medical services and outdoor use by home healthcare *patients*).

E.4 Other attributes

The following other attributes are expected for respiratory *small-bore connectors*:

a) usability under stress (ignoring labels, attempting force-fit);

b) proximity of liquids, use of gloves;

c) proximity of other *connector*-bearing equipment.

E.5 Generic *user* needs

The following *user* needs attributes were considered in the design of the respiratory *small-bore connectors*:

a) minimal healthcare *user* training on the use of *connectors*;

b) easy to manipulate without the use of tools. Ease of assembly/disassembly with fingertip control, especially in wet environments and/or use of gloves;

c) will not misconnect to other *small-bore connectors* not intended for the same purpose in the environment of use (see ISO 80369-1);

d) shall not leak under *normal use*;

e) security/integrity of the *connection*. Cannot unintentionally self-disconnect;

f) low dead space;

g) compatible with disinfection, decontamination, sterilization, and reprocessing environments.

Annex F
(informative)

Summary of *small-bore connector* design requirementsfor *respiratory applications*

Table F.1 is a summary of the design requirements for the R1 *connector* for *breathing systems*.

Table F.1 — R1 *connector*-specific design requirements

	Criteria		Requirements	Remarks
1	**Fluid type**	a) Liquid b) Gas c) Both	c)	
2	**Operating pressure range**	maximum pressure minimum pressure sub-atmospheric? (yes/no)	125 hPa (ambient pressure) –200 hPa yes	125 hPa is the single fault condition limit for a *breathing system*.
3	**Pressure range**	minimum maximum	0 hPa (ambient pressure) 150 hPa	
4	**Is there a need for a leak test?**	a) No b) Yes Reference for *test method*	b) 0,1 ml/min	
5	**Flowrate range**	minimum maximum	0 l/min 15 l/min	
6a	**Internal diameter range (through bore) *cone***	minimum maximum	1,00 mm 2,95 mm	
6b	**Internal diameter range (through bore) *socket***	minimum maximum	1,00 mm 2,70 mm	
7	**Temperature range**	minimum maximum	–40 °C +60 °C	
8	**Minimum range of *connector* mating diameters**	minimum maximum	–	Not compatible with *Luer connector* and other *small-bore connectors* of this series.
9	**General layout**	a) Parallel-sided, O-ring seal b) Parallel-sided, other seal c) Conical d) Other (specify)	c)	Conical, tip seal
10	**Method of keying**	a) Collar b) Plug c) Other (specify)	none	

Table F.1 *(continued)*

	Criteria		Requirements	Remarks
11	**Quick release?**	a) No b) Yes i) single-handed operation ii) double-handed operation	a)	
12	**Positive locking/unlocking feature?**	a) No b) Yes	a)	
13	**Need for visual indication of locking status?**	a) No b) Yes	a)	
14	**Need for indication of evidence of tampering?**	a) No b) Yes	a)	
15	**Need for a syringe in the *application*?**	a) No b) Yes	b)	There is a need to inject pharmaceuticals into the *breathing system.*
16	**Need for an absence of sharp edges?**	a) No b) Yes	b)	
17	**Minimum axial force in *normal use*, to remain attached**	force Reference for *test method*	35 N	Same as *Luer connector*
18	**Construction materials** (excluding seals)	a) Modulus of elasticity	> 700 MPa	
19	**Need for use of soft sealing material?**	a) No b) yes	a)	
20	**MRI compatibility?**	a) No, with labelling b) No, without labelling c) Yes, with labelling d) Yes, without labelling	b) or d)	Some uses might require MRI compatibility.
21	**Stress-cracking resistance?**	a) No b) Yes Specify limits	b)	Same as *Luer connector*
22	**Externally, how is *connector* to be distinguishable from *Luer connector*?** (describe)		not required	
23	**Proposal for colour-coding?**	a) No b) Yes Reference standard	a)	
24	**Labelling/Symbols/Marking?** (e.g. not for IV)	a) No b) Yes	a)	
25	**Other method for indicating *intended use*?**	a) No b) Yes Indicate method	a)	