BS EN 15908:2010

BSI Standards Publication

Anaesthetic and respiratory equipment — Non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases

National foreword

This British Standard is the UK implementation of EN 15908:2010. It partially supersedes BS EN ISO 5359:2008. It is intended that EN ISO 5359:2008 will be revised to remove requirements for NIST connectors.

The UK participation in its preparation was entrusted to Technical Committee CH/121/6, Medical gas supply systems.

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

ISBN 978 0 580 65806 8

ICS 11.040.10

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 November 2010.

Amendments issued since publication

Date	Text affected

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 15908

October 2010

ICS 11.040.10

English Version

Anaesthetic and respiratory equipment - Non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases

Matériel respiratoire et anesthésique - Raccords basse pression à tête filetée non interchangeables (NIST) pour gaz médicaux

Anästhesie- und Beatmungsgeräte - Nichtverwechselbare Verbindungsstücke mit Schraubgewinde (NIST) für niedrigen Druck zur Verwendung mit medizinischen Gasen

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Ref. No. EN 15908:2010: E

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Foreword

This document (EN 15908:2010) has been prepared by Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment”, the secretariat of which is held by BSI.

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of an identical text or by endorsement, at the latest by April 2011, and conflicting national standards shall be withdrawn at the latest by April 2011.

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

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

Requirements for non-interchangeable screw-threaded (NIST) connectors are currently specified in EN ISO 5359:2008. The requirements for NIST connectors in EN 15908 are identical to those currently given in EN ISO 5359:2008 except for:

the allocation of connector B11 (allocated to carbon dioxide instead to carbon dioxide/oxygen mixture [CO_2 > 7 % (volume fraction)]);

the allocation of connector C 19 (allocated to carbon dioxide/oxygen mixture [CO_2 > 7 % (volume fraction)] instead to carbon dioxide).

It is intended that EN ISO 5359:2008 will be revised so as to delete the requirements for NIST connectors.

The requirements for NIST connectors in EN 15908 are identical to those given in EN 739:1998 (cancelled and replaced by EN ISO 5359:2008) except for:

the allocations of connectors B11 (allocated to carbon dioxide only);

the allocation of connector C19 (allocated to carbon dioxide/oxygen mixture [CO_2 > 7 % (volume fraction)] only);

the allocation of connector B12 to oxygen-enriched air;

the allocation of connector B15 to helium/oxygen mixture [O_2 < 20 % (volume fraction)] only;

the allocation of connector C20 to helium only.

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, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This European Standard has been prepared in response to the need for a safe method of connecting medical equipment intended to administer medical gases to patients. Medical gases are stored in cylinders or cryogenic vessels, or can be produced on site; several medical devices, e.g. pressure regulators, hose assemblies, flow-metering devices, lung ventilators, anaesthetic workstations can be fitted between the source of supply and the patient. At each interface gas-specific connectors are needed to ensure that the intended medical gas is administered to the patient.

While recognizing that no system is absolutely safe, this European Standard includes those requirements considered necessary to prevent foreseeable hazards arising from the use of connectors. Operators should be continually alert to the possibility of damage being caused by external factors, and therefore regular inspection should be undertaken to ensure that connectors continue to meet the requirements of this European Standard.

The choice of a single system of connectors to be used within the European Union will minimize the risks of cross connections and misconnections and ensure the free movement of medical devices intended to administer medical gases to patients.

1 Scope

1.1 This European Standard specifies requirements for connectors intended for use with medical gases.

1.2 This European Standard specifies the dimensions and the allocation of non-interchangeable screw-threaded (NIST) connectors intended to be used at nominal operating pressures not greater than 1 400 kPa.

NOTE As stated in EN ISO 5359, gas-specific quick-connectors conforming to EN ISO 9170-1 are considered as an alternative to NIST connectors.

1.3 The information to be supplied by the manufacturer is excluded from the scope of this European Standard because information about the use of NIST connectors is supplied by the manufacturer of each medical device to which the connectors are permanently fitted.

2 Normative references

The following referenced document is indispensable for the application 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.

EN ISO 14971, *Medical devices — Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

gas-specific

having characteristics which prevent interchangeability, thereby allowing assignment to only one gas service or vacuum service

3.2

medical gas

gas or mixture of gases intended to be administered to patients for therapeutic, diagnostic or prophylactic purposes, or for surgical tool applications

NOTE For the purposes of this European Standard, this term includes vacuum, air and nitrogen for driving surgical tools.

3.3

NIST connector

non-interchangeable screw-threaded connector

any of a range of male and female components intended to maintain gas-specificity by the allocation of a set of different diameters and a left-or right-hand screw thread to the mating components for each particular gas

4 General requirements

4.1 Safety

NIST connectors shall, when permanently fitted onto a medical device and operated in normal use and maintained according to the instructions of the manufacturer of the medical device, present no risks that are

not reduced to an acceptable level by using risk management procedures in accordance with EN ISO 14971 and which are connected with their intended application, in normal condition and in single fault condition.

4.2 Materials

Materials in contact with the medical gases during normal use shall be resistant to corrosion and compatible with oxygen, the other medical gases and their mixtures.

NOTE 1 Corrosion resistance includes resistance against moisture and surrounding materials.

NOTE 2 Compatibility with oxygen involves both combustibility and ease of ignition. Materials which burn in air will burn violently in pure oxygen. Many materials which do not burn in air will do so in pure oxygen, particularly under pressure. Similarly, materials which can be ignited in air require lower ignition energies for ignition in oxygen. Many such materials can be ignited by adiabatic compression produced when oxygen is rapidly introduced into a system initially at low pressure.

NOTE 3 EN ISO 15001 contains information on selection of metallic and non-metallic materials and other aspects of compatibility of equipment with oxygen.

4.3 Design, dimensions and allocation of NIST connectors

Design and dimensions of NIST body, nipple and nut shall comply with Figures 1, 2 and 3 and Tables 2, 3 and 4.

Allocation of NIST connectors shall comply with Table 1.

Table 1 — NIST connector allocation – Right-hand thread

Connector reference	Gas
A1	Medical air/oxygen mixture
A2	Oxygen/nitrous oxide mixture [O_2 = 50 % (volume fraction)]
A3	Medical air
A4	Nitrous oxide
A5	Nitrous oxide/oxygen mixtures [N_2O < 80 % (volume fraction)]
A6	Air for driving surgical tools
A7	Not allocated
A8	Oxygen
A9	Not allocated
A10	Vacuum
B11	Carbon dioxide
B12	Oxygen-enriched air
B13	Oxygen/carbon dioxide mixture [CO_2 ≤ 7 % (volume fraction)]
B14	Helium/oxygen mixture [He ≤ 80 % (volume fraction)]
B15	Helium/oxygen mixture [O_2 < 20 % (volume fraction)]
B16	Xenon
B17	Special gas mixture
B18	Nitrogen for driving surgical tools
C19	Carbon dioxide /oxygen mixture [CO_2 > 7 % (volume fraction)]
C20	Helium
C21	Medical air/helium/carbon monoxide [CO < 1 % (volume fraction)]
C22	Not allocated
C23	Not allocated
C24	Not allocated

NOTE Left-hand threads have not been allocated.

Table 2 — Indexing diameters for NIST body (see Figure 1)

Dimensions in millimetres

Connector reference	Dimension B	Dimension C	Dimension D
A1	8		17
A2	8,5		16,5
A3	9 +0,09 0		16
A4	9,5		15,5
A5	10		15 + 0,11 0
A6	10,5	12,5 00,043 +	14,5
A7	11 +0,11 0		14
A8	11,5		13,5
A9	12		13
A10	12,5 +0,043 0		12,5 00,043 +
B11	7,5		14,5
B12	8		14
B13	8,5 0,09 +		13,5 0,11 + 0
B14	9		13
B15	9,5	11 00,043 +	12,5
B16	10		12
B17	10,5 +0,11 0		
B18	11 + 0,043 0		11 +00,043
C19	7,5		12,5
C20	8 +0,09 0		12 +0,11 0
C21	8,5		11,5 C22
9	10	+00,043	11
C23	9,5		10,5

C24	10	+0,043 0	10	00,043 +

Table 3 — Indexing diameters for NIST nipple (see Figure 2)

Dimensions in millimetres

Connector reference	Dimension E	Dimension F	Dimension G	Dimension H	Dimension I
A1	17		8		
A2	16,5		8,5 $^{0}_{-0,10}$		
A3	16		9		
A4	15,5		9,5		
A5	15		10		
A6	14,5	12,5 $^{0}_{-0,10}$			
			10,5	8,5 $^{0}_{-0,10}$	3,3 $^{0}_{-0,20}$
A7	14		11		
A8	13,5		11,5 $^{0}_{-0,10}$		
A9	13		12		
A10	12,5		12,5		
B11	14,5 $^{0}_{-0,10}$				
B12	14		8		
B13	13,5		8,5		
B14	13	11 $^{0}_{-0,10}$			
B15	12,5		9,5 $^{0}_{-0,10}$		
B16	12		10		
B17	11,5		10,5		
B18	11		11 $^{0}_{-0,10}$		2,5 $^{0}_{-0,20}$
C19	12,5		7,5		
C20	12		8		
C21	11,5	10 $^{0}_{-0,10}$			
C22	11		9		
C23	10,5		9,5		
C24	10		10		

Table 4 — Dimensions of "O" rings

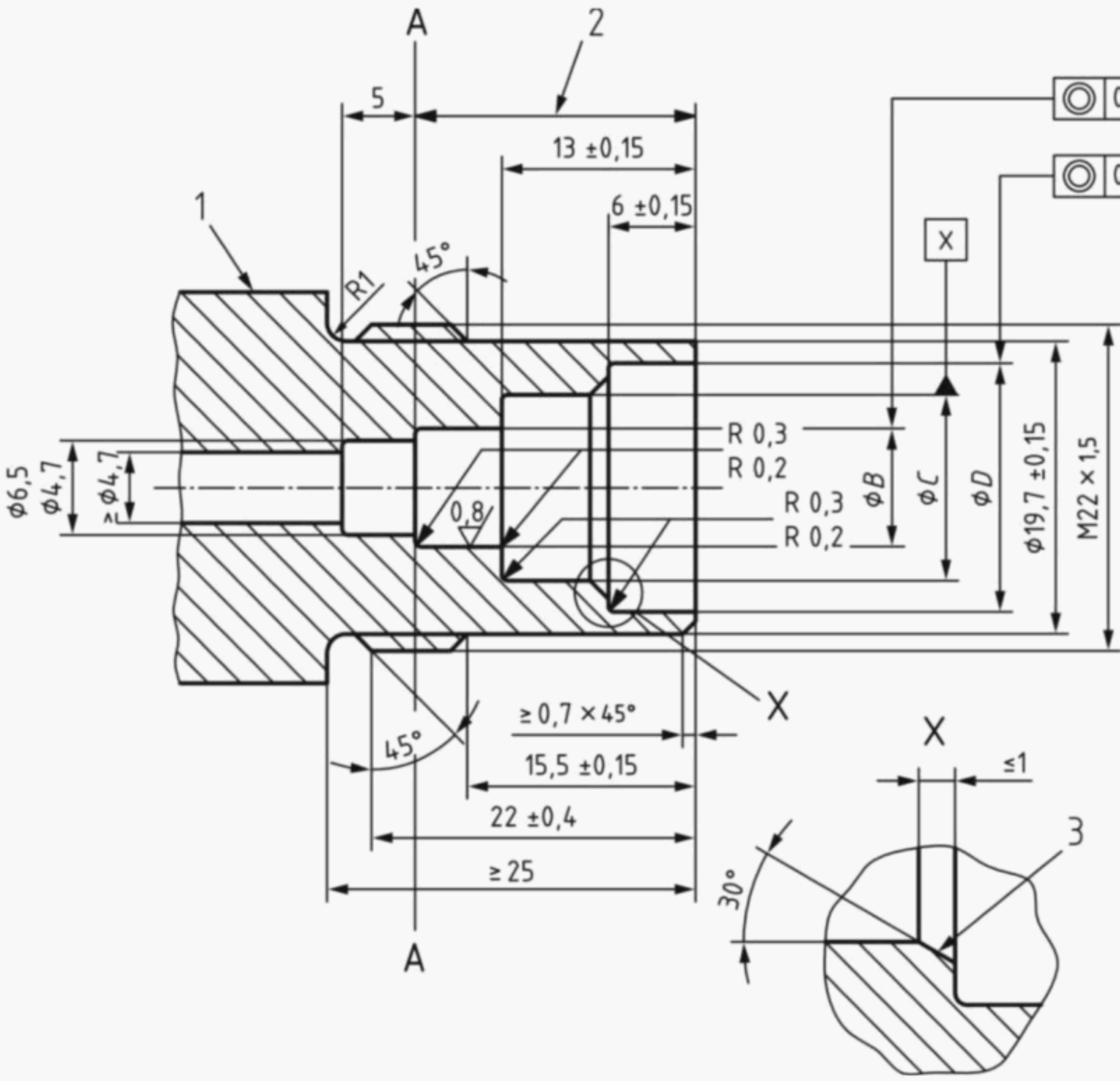
Dimensions in millimetres

Range	Internal diameter	Internal diameter tolerance	Section diameter	Section diameter tolerance
A	7,6	± 0,15	2,4	± 0,08
B	8,1	± 0,15	1,6	± 0,08
C	7,1	± 0,15	1,6	± 0,08

NOTE 1 Recommended hardness 75° IRHD.

NOTE 2 These dimensions are based upon BS 4518. For A, B and C ranges the "O" rings are identified in BS 4518 with the reference numbers 0076-24, 0081-16 and 0071-16 respectively.

Dimensions in millimetres



Key

1 position for marking gas identification symbol

2 A range = 19 ± 0,15; B range = 25 ± 0,15; C range = 31 ± 0,15

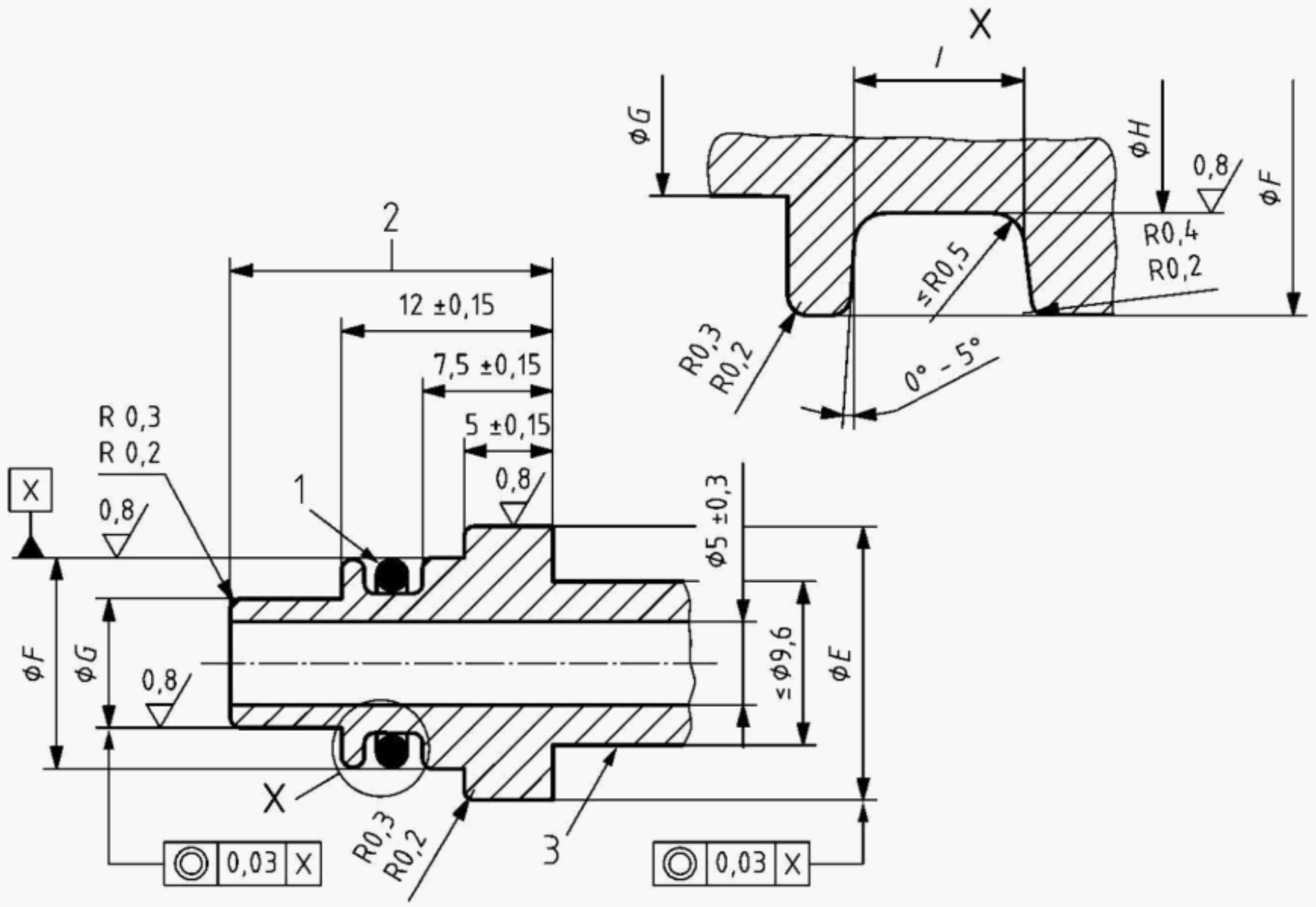
3 for connectors number A10, B18 and C24, the 12,5 mm/11 mm/10mm diameters extend over the full depths of 19 mm/25mm/31 mm respectively and this chamfer will appear at the nose of the fitting

surface finish shall be 1,6 unless otherwise stated

NOTE Diameters 6,5 and 4,7 and the location of face AA are critical. If this face is movable, for example when it forms part of a check valve, it is essential that means are provided to prevent its movement to a depth greater than 19 mm/25 mm/31 mm. See Table 2 for dimensions B, C and D.

Figure 1 — NIST body

Dimensions in millimetres



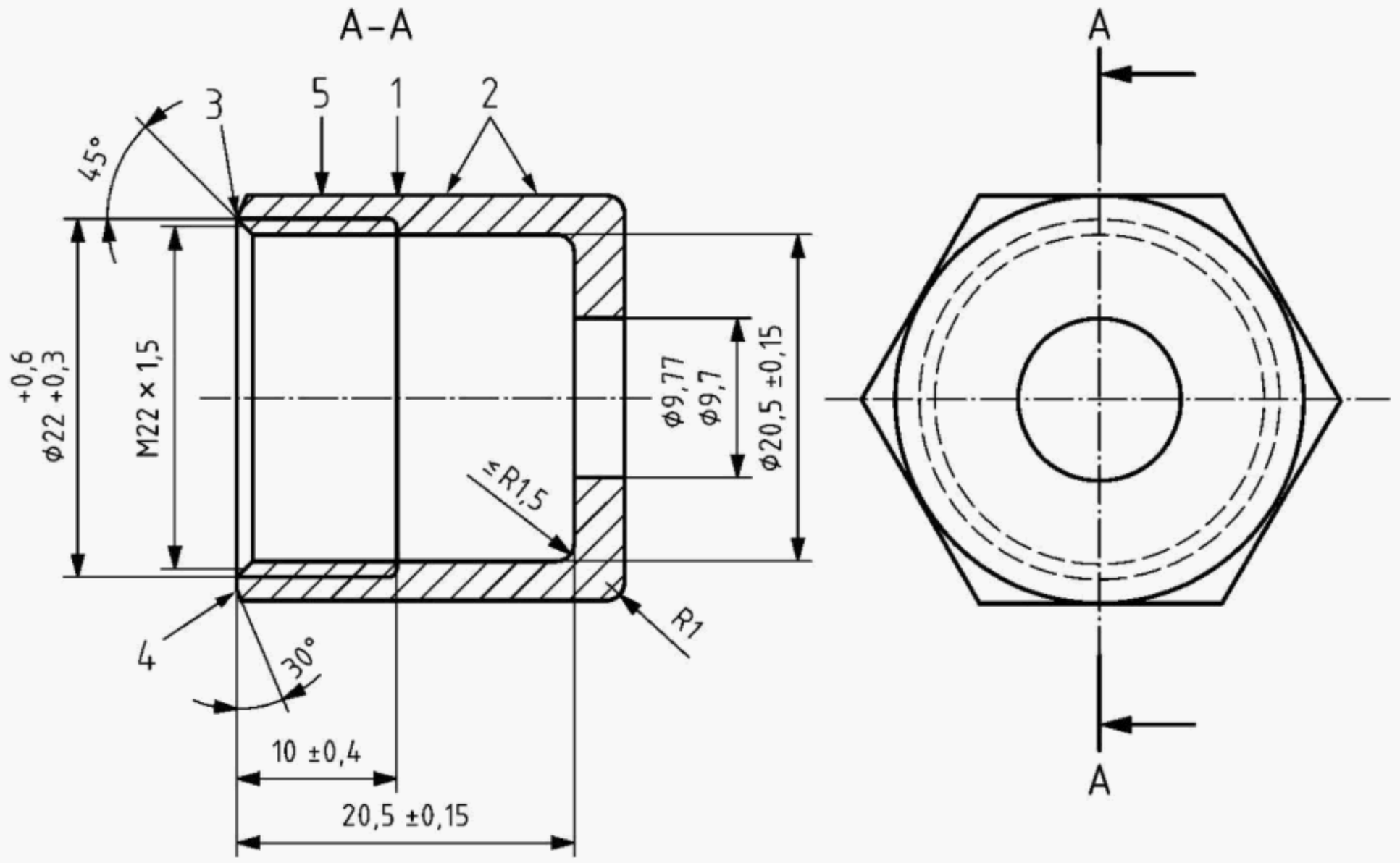
Key

1	"O" ring (dimensions given in Table 4)
2	A range: 18,5 ± 0,15, use "O" ring No 0076-24
	B range: 24,5 ± 0,15, use "O" ring No 0081-16
	C range: 30,5 ± 0,15, use "O" ring No 0071-16
3	position for marking gas identification symbol
	surface finish shall be 1,6 unless otherwise stated

NOTE Gas-tightness and smooth operation are best achieved when the "O" ring is compressed between 0,66 mm and 0,19 mm on diameter under maximum and minimum tolerancing conditions. See Table 3 for dimensions E, F, G, H and I.

Figure 2 — NIST nipple

Dimensions in millimetres



Key

1 notch with Vee tool across corners of hexagon to depth of flat for identification of left-hand nuts only

2 this area should preferably be knurled

3 chamfer to root of the thread

4 external chamfer

5 position for marking gas identification symbol

surface finish shall be 1,6 unless otherwise stated

NOTE External shape and dimensions can be varied to suit the materials used.

Figure 3 — NIST nut

5 Marking

The connectors shall be durably and legibly marked with the symbol of the relevant gas in accordance with Table 5.

NOTE In addition to the symbol, the name of the gas may be used.

The test for the durability of markings is given in Clause 6.

6 Test for durability of markings

The marking shall be legible to a person having visual acuity (corrected if necessary) of 1 standing 0,5 m from the connector at an illuminance of 215 lux.

Rub the markings by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with methylated spirit and then for 15 s with a cloth rag soaked with isopropyl alcohol. Carry out these tests at ambient temperature. Verify that the markings are still legible.

Table 5 — Marking

Medical gas or mixture	Symbol
Oxygen	O_2
Nitrous oxide	N_2O
Oxygen/nitrous oxide mixture O_2= 50 % (volume fraction) Nitrous oxide/oxygen mixtures	O_2/N_2O
 N_2O < 80 % (volume fraction)	N_2O/O_2 [b]
Medical air	Air [a]
Air for driving surgical tools	Air – 800 [a]
Vacuum	Vac [a]
Medical air/oxygen mixture	Air/O_2 [a]
Nitrogen for driving surgical tools	N_2 - 800
Helium	He
Helium/oxygen mixture O_2 < 20 % (volume fraction)	He/O_2
Helium/oxygen mixture He ≤ 80 % (volume fraction)	O_2/He
Oxygen/carbon dioxide mixture CO_2 ≤ 7 % (volume fraction)	O_2/CO_2
Carbon dioxide	CO_2
Carbon dioxide/oxygen mixture CO_2 > 7 % (volume fraction)	CO_2/O_2
Xenon	Xe
Oxygen-enriched air	[c]
Medical air/helium/carbon monoxide CO < 1 % (volume fraction)	 LFT [d]
Special gas mixture	[e]

[a] National languages may be used for Air and Vacuum.

[b] Except for oxygen/nitrous oxide mixture [O_2 = 50 % (volume fraction)].

[c] To be defined by the European Pharmacopoeia.

[d] Lung Function Test.

[e] For limited experimental applications. Symbols for special gas mixtures should conform to the chemical symbols of the components.

Annex A

(informative)

Environmental aspects

The environmental aspects are dealt with in each European Standard concerning medical devices fitted with NITS connectors.

Annex ZA

(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC Medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC Medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC Medical devices

Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC Medical devices	Qualifying remarks/Notes
4.1	1	
4.1	2	
4.2	7.1	
4.2	7.3	
4.2	9.3	
4.3, Tables 2 and 3	4, 5	
4.3, Table 4	7.5	
4.3, Tables 1, 2 and 3 and Figures 1, 2 and 3	9.1	
4.3, Tables 1, 2 and 3 and Figures 1, 2 and 3	12.7.4	
4.3, Tables 1, 2 and 3 and Figures 1, 2 and 3	12.8.1	
5 and Table 5	13.1	
6	13.1	
Figure 1, item 1	13.2	
Figure 2, item 3	13.2	
Figure 3, item 5	13.2	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

Bibliography

[1] EN ISO 5359:2008, *Low-pressure hose assemblies for use with medical gases (ISO 5359:2008)*

[2] EN ISO 9170-1:2008, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum (ISO 9170-1:2008)*

[3] EN ISO 15001, *Anaesthetic and respiratory equipment — Compatibility with oxygen (ISO 15001:2010)*

[4] EN 739:1998, *Low-pressure hose assemblies for use with medical gases*

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