
Cevni priključki s cevmi iz nekovinskih materialov za uporabo v farmacevtski in biotehnoški industriji - Silikonske gumijaste cevi

Hose assemblies for use in the pharmaceutical and biotechnological industry with hoses of non-metallic materials - Silicone rubber hoses

Schlauchleitungen für den Einsatz in der pharmazeutischen und biotechnischen Industrie mit Schläuchen aus nichtmetallischen Werkstoffen - Schläuche aus Siliconkautschuk

Flexibles pour utilisation dans les industries pharmaceutique et biotechnologique avec tuyaux sans matériaux métalliques - Tuyaux en silicone

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EUROPEAN STANDARD

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Rubber and plastics hoses and hose assemblies for use in the pharmaceutical and biotechnological industry - Silicone rubber hoses

Tuyaux et flexibles en caoutchouc et en plastique pour
utilisation dans les industries pharmaceutique et
biotechnologique - Tuyaux en silicone

Gummi- und Kunststoffschläuche und -
schlauchleitungen für den Einsatz in der
pharmazeutischen und biotechnischen Industrie -
Schläuche aus Siliconkautschuk

This European Standard was approved by CEN on 20 February 2017.

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European foreword

This document (EN 16821:2017) has been prepared by Technical Committee CEN/TC 218 “Rubber and plastic hoses and hose assemblies”, 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of an identical text or by endorsement, at the latest by December 2017, and conflicting national standards shall be withdrawn at the latest by December 2017.

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EN 16821:2017 (E)**1 Scope**

This European Standard applies to type 1 to type 3 hose assemblies with hoses made of silicone rubber for the transport of liquid or powdery substances in the pharmaceutical and the biotechnological industries. It specifies the classification, manufacturing and testing of as well as the materials, requirements and quality surveillance for hose assemblies.

These hose assemblies are intended to be used with the relevant substances at temperatures in the range from $-40\text{ °C}^{1)}$ to $+150\text{ °C}$ and at operating pressures from $-0,9\text{ bar}$ (vacuum) to 10 bar (see Table 1). These hose assemblies are not electrically conductive. The danger of static charging shall be considered on a case-by-case basis.

Hose assemblies in accordance with this standard are classified into two designs, A and B (see 3.2).

Attention is called to the fact that for certain applications the relevant legal regulations such as the Pressure Equipment Directive 2014/68/EU (PED) need to be complied with.

2 Normative references

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

EN 10088-2:2014, *Stainless steels - Part 2: Technical delivery conditions for sheet/plate and strip of corrosion resisting steels for general purposes*

EN 10204, *Metallic products - Types of inspection documents*

EN 12351, *Industrial valves - Protective caps for valves with flanged connections*

EN ISO 1043-1, *Plastics - Symbols and abbreviated terms - Part 1: Basic polymers and their special characteristics (ISO 1043-1)*

EN ISO 1402, *Rubber and plastics hoses and hose assemblies - Hydrostatic testing (ISO 1402)*

EN ISO 2078, *Textile glass - Yarns - Designation (ISO 2078)*

EN ISO 5817, *Welding - Fusion-welded joints in steel, nickel, titanium and their alloys (beam welding excluded) - Quality levels for imperfections (ISO 5817)*

EN ISO 7233, *Rubber and plastics hoses and hose assemblies - Determination of resistance to vacuum (ISO 7233)*

EN ISO 7326, *Rubber and plastics hoses - Assessment of ozone resistance under static conditions (ISO 7326)*

EN ISO 10619-1, *Rubber and plastics hoses and tubing - Measurement of flexibility and stiffness - Part 1: Bending tests at ambient temperature (ISO 10619-1)*

1) Individual tests in the form of bending tests under very low temperatures are currently being performed by, for example, Department WTD 51 of the Bundesamt für Wehrtechnik und Beschaffung (BWB, German Federal Office of Military Engineering and Procurement), Universitätsstraße 5, 56070 Koblenz.

EN ISO 10619-2, *Rubber and plastics hoses and tubing - Measurement of flexibility and stiffness - Part 2: Bending tests at sub-ambient temperatures (ISO 10619-2)*

ISO 1629, *Rubber and latices — Nomenclature*

ISO 7619-1, *Rubber, vulcanized or thermoplastic — Determination of indentation hardness — Part 1: Durometer method (Shore hardness)*

ISO 7619-2, *Rubber, vulcanized or thermoplastic — Determination of indentation hardness — Part 2: IRHD pocket meter method*

3 Classifications and conditions of use

3.1 Hose types

Due to the operational requirements and the manufacturing conditions, the structural design of hose assemblies in accordance with this standard can vary considerably. A selection of possible hose types/designs is given in Table 1. Other designs are permissible, provided they are at least technically equivalent and conform to the requirements of Clause 6.

Table 1 — Hose types

Type	Structure	Inside diameter mm	Minimum working pressure ^a bar	Maximum working pressure bar
1	hose made of silicone without reinforcing member (only silicone lining)	6	-0,7	0,8
		8	-0,7	0,7
		10	-0,7	0,6
		13	-0,7	0,5
		15	-0,7	0,4
		16	-0,7	0,3
		19	-0,5	0,2
		25	-0,5	0,1
		32	-0,5	0,07
		38	-0,4	0,05
2	hose made of silicone lining with textile reinforcing member and silicone cover	6	-0,85	8,0
		8	-0,85	7,0
		10	-0,85	6,0
		13	-0,8	6,0
		15	-0,8	5,0
		16	-0,8	5,0

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Type	Structure	Inside diameter	Minimum working pressure ^a	Maximum working pressure
		19	-0,8	5,0
		25	-0,75	3,0
		32	-0,7	2,0
		38	-0,6	2,0
		50	-0,4	1,0
3	hose made of silicone lining with textile reinforcing members, incorporated high-grade steel helix and silicone cover	13	-0,9	10
		19	-0,9	10
		25	-0,9	10
		38	-0,9	10
		50	-0,9	8,5
^a Pressure < 0 bar (vacuum).				

Hose assemblies of types 1 to 3 in accordance with this standard shall have a Shore hardness of between 50 Shore A and 70 Shore A, determined in accordance with ISO 7619-1 or ISO 7619-2.

Hose assemblies in accordance with this standard shall be autoclavable (vapour sterilization) for at least 30 min at 140 °C. Each vapour application accelerates the natural ageing process of the silicone.

Pressures and temperatures other than those given in the scope can be agreed upon between the manufacturer and the user.

3.2 Hose designs

Hoses in accordance with this standard are classified into two designs:

- design A: FDA conformity of all hose materials;
- design B: FDA conformity of all parts of the hose lining in contact with the product.

3.3 Hose assembly designs

Hose assemblies in accordance with this standard are classified into two designs:

- design A: FDA conformity of all hose materials and end fittings;
- design B: FDA conformity of all parts of the hose lining in contact with the product and end fittings.

4 Dimensions

4.1 Inside diameter, wall thickness of the hoses

In Table 2, the usual inside diameters and the corresponding typical wall thicknesses for the different hose types are given.

Table 2 — Dimensions²⁾

Inside diameter		Type 1		Type 2		Type 3	
Nominal size	Tolerances mm	Wall thickness		Wall thickness		Wall thickness	
		Dimensions mm	Tolerances mm	Dimensions mm	Tolerances mm	Dimensions mm	Tolerances mm
6	±0,3	2	±0,2	3,2	±0,3	—	—
8	±0,3	2		3,2			
10	±0,4	3		3,5			
13	±0,4	3		4,0		5,2	±0,5
15	±0,5	3		4,5		—	—
16	±0,5	3		4,8		—	—
19	±0,7	3	4,8	5,2		±0,5	
25	±0,8	4	6,0	5,2		±0,5	
32	±1,0	4	6,0	—		—	
38	±1,5	4	7,0	5,2		±0,5	
50	±2,0	5	7,0	5,2		±0,5	

4.2 Length and tolerances for the hose assemblies

The length of the hose assembly is considered to be the installation length measured between the sealing surfaces of the end fittings.

The tolerance for hose assemblies shall be $\begin{matrix} +3,0 \\ -2,0 \end{matrix} \%$.

Narrower tolerances shall be agreed upon with the manufacturer of the hose assembly.

4.3 Minimum bend radius

The information given in Table 3 applies to the minimum bend radius of type 1 to type 3 hose assemblies.

²⁾ Other dimensions can be agreed upon between the user and the manufacturer.