
Gumene in polimerne cevi in cevni priključki za uporabo v farmacevtski in biotehnoški industriji - Vezane elastomerne cevi s podlogo ali brez nje

Rubber and plastics hoses and hose assemblies for use in the pharmaceutical and biotechnological industry - Bonded elastomeric hoses with or without a lining

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

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

Ta slovenski standard je istoveten z: EN 16820:2017

ICS:

11.120.99	Drugi standardi v zvezi s farmacijo	Other standards related to pharmaceuticals
83.140.40	Gumene cevi	Hoses

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Rubber and plastics hoses and hose assemblies for use in the pharmaceutical and biotechnological industry - Bonded elastomeric hoses with or without a lining

Tuyaux et flexibles en caoutchouc et en plastique pour utilisation dans l'industrie pharmaceutique et biotechnologique - Tuyaux liés en élastomère avec ou sans tube intérieur

Gummi- und Kunststoffschläuche und -schlauchleitungen für den Einsatz in der pharmazeutischen und biotechnischen Industrie - Verbundene Schläuche aus Elastomeren mit oder ohne Innenschicht

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

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

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EN 16820:2017 (E)**European foreword**

This document (EN 16820:2017) 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of an identical text or by endorsement, at the latest by December 2017, and conflicting national standards shall be withdrawn at the latest by December 2017.

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.

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1 Scope

This European Standard applies to type D and type SD hose assemblies with hoses made of elastomers and bonded plastics for the transport of gaseous, vaporous, 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 -30 °C to $+100\text{ °C}$, depending on the medium, and at operating pressures from $-0,9\text{ bar}$ (vacuum) to 10 bar (see Tables 2 and 3). For hoses with a lining made of PTFE and derivatives, temperatures from -30 °C to $+140\text{ °C}$ are permissible.

Hose assemblies in accordance with this standard are classified into two designs, A and B (see 3.3).

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 1092-1, *Flanges and their joints — Circular flanges for pipes, valves, fittings and accessories, PN designated — Part 1: Steel flanges*

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

EN 10244-2, *Steel wire and wire products - Non-ferrous metallic coatings on steel wire - Part 2: Zinc or zinc alloy coatings*

EN 10270-1, *Steel wire for mechanical springs - Part 1: Patented cold drawn unalloyed spring steel wire*

EN 10270-2, *Steel wire for mechanical springs - Part 2: Oil hardened and tempered spring steel wire*

EN 12115, *Rubber and thermoplastics hoses and hose assemblies for liquid or gaseous chemicals - Specification*

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

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

EN ISO 4671, *Rubber and plastics hoses and hose assemblies - Methods of measurement of the dimensions of hoses and the lengths of hose assemblies (ISO 4671)*

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 8031:2009, *Rubber and plastics hoses and hose assemblies - Determination of electrical resistance and conductivity (ISO 8031:2009)*

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EN ISO 8033, *Rubber and plastics hoses - Determination of adhesion between components (ISO 8033)*

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)*

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 37, *Rubber, vulcanized or thermoplastic — Determination of tensile stress-strain properties*

ISO 188, *Rubber, vulcanized or thermoplastic — Accelerated ageing and heat resistance tests*

ISO 1817, *Rubber, vulcanized or thermoplastic — Determination of the effect of liquids*

BS 3592-1:1986, *Steel wire for hose reinforcement — Specification for coated round and flat steel wire for rubber hose reinforcement*

IEC/TS 60079-32-1, *Explosive atmospheres — Part 32-1: Electrostatic hazard — Guidance*

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.

Table 1 — Hose types

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Type	Structure	Application limits/ operational data
D ^a	rubber hose with or without a plastics lining and with one or several reinforcement(s) (pressure carrier)	see Tables 2 and 3
SD ^b	rubber hose with or without a plastics lining and with one or several reinforcement(s) (pressure carrier) offering sufficient form stability for suction application or with one or several integrated helix(es), respectively	
^a D is a pressure hose. ^b SD is a suction and discharge hose.		

Hose assemblies in accordance with this standard shall be autoclavable (vapour sterilization) for at least 30 min at 130 °C.

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

3.2 Hose grades

Hoses and hose assemblies for this application shall be classified into five grades:

- grade I: electrically insulated (no electrical bonding AND no static-dissipative layers);
- grade M: electrically bonded without static-dissipative lining or cover;
- grade Ω : electrically conductive;
- grade M/T: electrically bonded and with an electrical volume resistance through the hose wall not exceeding $10^9 \Omega$;
- grade Ω /T: electrically conductive and with an electrical volume resistance through the hose wall not exceeding $10^9 \Omega$.

3.3 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.

3.4 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, minimum thickness of the lining, bending radii

Depending on the type, the following shall conform to the values in Tables 2 and 3:

- the inside diameter of hoses;
- the minimum thickness of the lining;
- the minimum bending radius.

Table 2 — Dimensions and bending radii for hose type D

Nominal size	Inside diameter		Outside diameter		Minimum thickness		Minimum bending radius ^b	Vacuum stability			
	mm		mm		mm						
	Dimensions	Tolerances	Dimensions	Tolerances	Lining ^a	Hose cover	mm	bar			
13	13,0	±0,5	23,0	±1,0	2,0	1,6	90	-0,5			
16	16		26,0				100				
19	19,0		31,0				125				
25	25,0		37,0				150	-0,4			
32	32,0		44,0				175				
38	38,0		51,0				225				
50	50,0	±0,7	66,0	±1,2	2,0	2,0	275	-0,3			
51	51,0		67,0				275				
63	63,0	±0,8	79,0				±1,6	2,0	2,0	300	—
75	75,0		91,0							350 ^c	
76	76,0		92,0							350 ^c	
100	100,0		116,0							450 ^c	
101,5	101,5		118,0	450 ^c							

^a The dimensions for the minimum thickness of the lining are not applicable for hoses made of PE-X/UPE and fluoro-plastics. The thickness of these materials shall be at least 0,4 mm.

^b The bending radii given are not applicable for hoses made of PE-X/UPE and fluoro-plastics; in these cases they shall be 1,5 times as large.

^c Only applicable for operation at minimum 1 bar, otherwise the hose will kink.

Table 3 — Dimensions and bending radii for hose type SD

Nominal size	Inside diameter		Outside diameter		Minimum thickness		Minimum bending radius mm ^b	Vacuum stability bar
	mm		mm		mm			
	Dimensions	Tolerances	Dimensions	Tolerances	Lining ^a	Hose cover		
19	19,0	±0,5	31,0	±1,0	1,6	1,6	125	-0,8
25	25,0		37,0				150	
32	32,0		44,0				175	
38	38,0		51,0				225	
50	50,0	±0,7	66,0	±1,2	1,7	1,7	275	
51	51,0		67,0				275	
63	63,0	±0,8	79,0	±1,2	1,8	1,7	300	
75	75,0		91,0				350	
76	76,0		92,0				350	
100	100,0		116,0	±1,6		2,0	450	
101,5	101,5		118,0				450	

^a The dimensions for the minimum thickness of the lining are not applicable for hoses made of PE-X/UPE and fluoro-plastics. The thickness of these materials shall be at least 0,4 mm.

^b The bending radii given are not applicable for hoses made of PE-X/UPE and fluoro-plastics; in these cases they shall be 1,5 times as large.

4.2 Concentricity

When determined in accordance with EN ISO 4671, on the basis of all readings of the dial gauge between the inside diameter and the surface of the cover, the concentricity shall be $\leq 1,0$ mm for hoses with a nominal size ≤ 50 and $\leq 1,5$ mm for hoses with a nominal size > 50 .

4.3 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 permissible tolerance is ${}_{-10}^{+15}$ mm for hose assemblies with a length of up to and including 1 000 mm.

The permissible tolerance is ${}_{-1,0}^{+1,5}$ % for hose assemblies with a length of more than 1 000 mm.

4.4 Minimum bending radius

The dimensions given in Tables 2 and 3 apply to the minimum bending radius of type D and type SD hose assemblies.

Other dimensions will be agreed upon between the user and the manufacturer.