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English Version

## 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 draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 218.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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EUROPEAN COMMITTEE FOR STANDARDIZATION  
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## European foreword

This document (prEN 16820:2024) has been prepared by Technical Committee CEN/TC 218 “Rubber and plastics hoses and hose assemblies”, the secretariat of which is held by BSI.

This document is currently submitted to the CEN Enquiry.

This document will supersede EN 16820:2017.

This document includes the following significant technical changes with respect to EN 16820:2017:

- In 4.1, Table 1 the term “design” has been changed to “type”;
- In 4.2, an error in the value for electrical volume resistance has been corrected;
- In 4.3 and 4.4 the term “design” has been changed to “type”;
- In Clause 6 the reference to EU Regulation 1935/2004 has been removed;
- In Clause 8, Figure 1 has been corrected;

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**prEN 16820:2024 (E)****1 Scope**

This document 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  $-30\text{ °C}$  to  $+100\text{ °C}$ , depending on the medium, and at operating pressures from  $-0,9\text{ bar}$  (vacuum) to  $10\text{ bar}$  (see Table 2 and Table 3). For hoses with a lining made of PTFE and derivatives, temperatures from  $-30\text{ °C}$  to  $+140\text{ °C}$  are permissible.

Hose assemblies in accordance with this document are classified into four types, A – D, A – SD, B – D, B – SD.

**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.

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 1402:2021, *Rubber and plastics hoses and hose assemblies - Hydrostatic testing (ISO 1402:2021)*

EN ISO 4671:2022, *Rubber and plastics hoses and hose assemblies - Methods of measurement of the dimensions of hoses and the lengths of hose assemblies (ISO 4671:2022)*

EN ISO 5817:2023, *Welding - Fusion-welded joints in steel, nickel, titanium and their alloys (beam welding excluded) - Quality levels for imperfections (ISO 5817:2023)*

EN ISO 7233:2021, *Rubber and plastics hoses and hose assemblies - Determination of resistance to vacuum (ISO 7233:2021)*

EN ISO 7326:2016, *Rubber and plastics hoses - Assessment of ozone resistance under static conditions (ISO 7326:2016)*

EN ISO 8031:2020, *Rubber and plastics hoses and hose assemblies - Determination of electrical resistance and conductivity (ISO 8031:2020)*

EN ISO 8033:2017, *Rubber and plastics hoses - Determination of adhesion between components (ISO 8033:2016)*

EN ISO 10619-1:2018, *Rubber and plastics hoses and tubing - Measurement of flexibility and stiffness - Part 1: Bending tests at ambient temperature (ISO 10619-1:2017)*

EN ISO 10619-2:2021, *Rubber and plastics hoses and tubing - Measurement of flexibility and stiffness - Part 2: Bending tests at sub-ambient temperatures (ISO 10619-2:2021)*

IEC/TS 60079-32-1:2018, *Explosive atmospheres - Part 32-1: Electrostatic hazards, guidance*

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*

### 3 Terms and definitions

No terms and definitions are listed in this document.

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/>

### 4 Classifications and conditions of use

#### 4.1 Hose types

Due to the operational requirements and the manufacturing conditions, the structural design of hose assemblies in accordance with this document can vary considerably. A selection of possible hose/hose assembly types is given in Table 1 and Table 2

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Table 1 — Hose types<sup>d</sup>

Type	Conformity	Structure	Application limits/operational data
A – D <sup>a</sup>	Conformity of all components of the hose with the requirements of the pharmaceutical and biotechnology industry <sup>c</sup>	rubber hose with or without a plastics lining and with one or several reinforcement(s) (pressure carrier)	see Table 3 and Table 4
A – SD <sup>b</sup>		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	
B – D <sup>a</sup>	Conformity of all components of the lining of the hose, which is in contact with the product, with the requirements of the pharmaceutical and biotechnology industry <sup>c</sup>	rubber hose with or without a plastics lining and with one or several reinforcement(s) (pressure carrier)	
B – SD <sup>b</sup>		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	
<sup>a</sup> D is a pressure hose. <sup>b</sup> SD is a suction and discharge hose. <sup>c</sup> e.g. FDA, USP Class VI or EN ISO 10993-5:2009 according Clause 6 <sup>d</sup> marking of the hose according 11.1			



Table 2 —Hose assembly types<sup>d, e</sup>

Type	Conformity	Structure	Application limits/ operational data
A – D <sup>a</sup>	Conformity of all components of the hose and end fittings with the requirements of the pharmaceutical and biotechnology industry <sup>c</sup>	rubber hose with or without a plastics lining and with one or several reinforcement(s) (pressure carrier)	see Table 3 and Table 4
A – SD <sup>b</sup>		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	
B – D	Conformity of all components of the inner hose liner and end fittings, which is in contact with the product, with the requirements of the pharmaceutical and biotechnology industry <sup>c</sup>	rubber hose with or without a plastics lining and with one or several reinforcement(s) (pressure carrier)	
B – SD <sup>b</sup>		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	
<sup>a</sup> D is a pressure hose. <sup>b</sup> SD is a suction and discharge hose. <sup>c</sup> e.g. FDA, USP Class VI or EN ISO 10993-5:2009 according Clause 6 <sup>d</sup> marking of the hose according 11.1 <sup>e</sup> marking of the coupling according 11.3			

Hose assemblies in accordance with this document 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.

#### 4.2 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;

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- grade  $\Omega$ : electrically conductive;
- grade M/T: electrically bonded and with an electrical volume resistance through the hose wall not exceeding  $10^9 \Omega$ ;
- grade  $\Omega$ /T: electrically conductive and with an electrical volume resistance through the hose wall not exceeding  $10^9 \Omega$ .

**5 Dimensions****5.1 Inside diameter, minimum thickness of the lining, bending radii**

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

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

**Table 3 — Dimensions and bending radii for hose type A - D / B - D**

Nominal size	Inside diameter		Outside diameter		Minimum thickness		Minimum bending radius <sup>b</sup> mm	Vacuum stability bar			
	Dimensions	Tolerances	Dimensions	Tolerances	Lining <sup>a</sup>	Hose cover					
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 <sup>c</sup>	
76	76,0		92,0							350 <sup>c</sup>	
100	100,0		116,0							450 <sup>c</sup>	
101,5	101,5		118,0	450 <sup>c</sup>							

<sup>a</sup> 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.

<sup>b</sup> 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.

<sup>c</sup> Only applicable for operation at minimum 1 bar, otherwise the hose will kink.