SLOVENSKI STANDARD
SIST EN 16820:2026

01-maj-2026

Gumene in polimerne cevi in cevni priključki za uporabo v farmacevtski in biotehnološki 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

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

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

Ta slovenski standard je istoveten z: **EN 16820:2026**

ICS:

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

SIST EN 16820:2026 **en,fr,de**

EUROPEAN STANDARD

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EN 16820

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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 assemblages 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 16 February 2026.

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

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European foreword

This document (EN 16820:2026) 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 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of an identical text or by endorsement, at the latest by September 2026, and conflicting national standards shall be withdrawn at the latest by September 2026.

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.

This document supersedes 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 Clause 6 the reference to EU Regulation 1935/2004 has been removed;

— In Clause 8, Figure 1 has been corrected;

— Normative Annex A “Test procedure to determine the electrical resistance through the wall of hoses” has been deleted.

Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organisations 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, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

1 Scope

This document is applicable 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 °C, depending on the medium, and at operating pressures from −0,9 bar (vacuum) to 10 bar (see Table 2 and Table 3). For hoses with a lining made of PTFE and derivatives, temperatures from −30 °C to +140 °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 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 5817:2023, *Welding — Fusion-welded joints in steel, nickel, titanium and their alloys (beam welding excluded) — Quality levels for imperfections (ISO 5817:2023)*

EN ISO 7233, *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 8031:2020, *Rubber and plastics hoses and hose assemblies — Determination of electrical resistance and conductivity (ISO 8031:2020)*

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

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.