STN

Hadice s koncovkami na použitie vo farmaceutickom a biotechnologickom priemysle, s hadicami z nekovových materiálov Elastomérne hadice s vložkou alebo bez vložky

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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

Táto norma obsahuje anglickú verziu európskej normy. This standard includes the English version of the European Standard.

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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 European Standard was approved by CEN on 20 February 2017.

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. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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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 $-30\,^{\circ}\text{C}$ to $+100\,^{\circ}\text{C}$, 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 $-30\,^{\circ}\text{C}$ to $+140\,^{\circ}\text{C}$ 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

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