SLOVENSKI STANDARD
SIST EN 13312-2:2002

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Biotehnologija - Merila za delovanje cevne napeljave in pripomočke - 2. del: Povezovalni elementi

Biotechnology - Performance criteria for piping and instrumentation - Part 2: Couplings

Biotechnik - Leistungskriterien für Leitungssysteme und Instrumentierung - Teil 2: Verbindungsstücke

Biotechnologie - Criteres de performance pour tuyauteries et instrumentation - Partie 2: Raccords

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Biotechnology - Performance criteria for piping and instrumentation - Part 2: Couplings

Biotechnologie - Critères de performance pour tuyauteries et instrumentation - Partie 2: Raccords

Biotechnik - Leistungskriterien für Leitungssysteme und Instrumentierung - Teil 2: Verbindungsstücke

This European Standard was approved by CEN on 13 January 2001.

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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 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

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Contents

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 233 "Biotechnology", the secretariat of which is held by AFNOR.

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of an identical text or by endorsement, at the latest by August 2001, and conflicting national standards shall be withdrawn at the latest by August 2001.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

This standard is one of a series of European Standards concerned with performance criteria for piping and instrumentation. These standards are :

EN 13312-1, *Biotechnology - Performance criteria for piping and instrumentation - Part 1 : General performance criteria.*

EN 13312-2, *Biotechnology - Performance criteria for piping and instrumentation - Part 2 : Couplings.*

EN 13312-3, *Biotechnology - Performance criteria for piping and instrumentation - Part 3 : Sampling and inoculation devices.*

EN 13312-4, *Biotechnology - Performance criteria for piping and instrumentation - Part 4 : Tubes and pipes.*

EN 13312-5, *Biotechnology - Performance criteria for piping and instrumentation - Part 5 : Valves.*

EN 13312-6, *Biotechnology - Performance criteria for piping and instrumentation - Part 6 : Equipment probes.*

This standard includes a Bibliography.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

Couplings are used for joining tubular sections, and for connecting other components of equipment into the process system, where equipment is designed to be disassembled. In many cases couplings are made of stainless steel and are used in all food, beverage, pharmaceutical and biotechnological processes.

Detailed design specifications are necessary to ensure interchangeability and connectability, since frequently the various parts of a coupling will be manufactured by different organisations. As an example, control and measuring devices are often supplied with couplings on the connecting ports which have to be secured to tube systems with mating parts and gaskets supplied by third parties.

Couplings are designed to be leakproof under normal operating conditions. In biotechnological applications they should in relevant cases prevent the release of microorganisms into the atmosphere and ingress into the process system. Couplings should enable process equipment to be cleaned in place or dismantled for manual cleaning and/or sterilization in an autoclave. Typical coupling standards are given in bibliography [3] to [10].

In relevant cases couplings themselves should be capable of being cleaned and/or sterilized in place.

The continuously reliable performance of a coupling is dependent on features and conditions which are not integral parts of this European Standard, and therefore attention is drawn to the recommendations for design, installation and maintenance in annex B.

Use of this European Standard will aid the equipment manufacturer in the classification of couplings with regard to safe performance in biotechnological processes. The classification is easily understandable and readily utilizable for the user and the regulatory authorities.

1 Scope

This European Standard specifies performance criteria for couplings used in biotechnological processes with respect to the potential hazards to the worker and the environment from microorganisms in use.

This European Standard applies where the intended use of the coupling includes hazardous or potentially hazardous microorganisms used in biotechnological processes or where exposure of the worker or the environment to such microorganisms is restricted for reasons of safety.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 13312-1:2001, *Biotechnology - Performance criteria for piping and instrumentation - Part 1: General performance criteria.*

3 Terms and definitions

For the purposes of this standard, the terms and definitions given in EN 13312-1:2001 apply.

4 Hazards

The following hazards shall be taken into account.

a) Release of microorganisms caused by :

- non-compatibility of couplings, gaskets and/or fittings ;

- misalignment of the coupling during assembly ;

- replacement of the specialised gaskets, specified for a particular process and coupling design, with similar product, for example 'O' rings, which are not suitable for the service demanded ;

- looseness of couplings in service resulting from expansion, contraction and vibrations ;

NOTE 1 The extent to which the gasket material can be compressed or expanded by mechanical, heat or vacuum conditions is controlled by the choice of coupling design, materials used and manufacturing tolerances.

- misalignment resulting from repetitive use of gaskets for clamp couplings.

b) Overtightening of couplings designed to have a seal which is flushed with the inner bore of the tube system can cause the gasket to extrude into the bore or can damage the surface of the seal, thereby reducing the effectiveness of cleaning and sterilization.

c) Protection of viable hazardous microorganisms in cracks and fissures within the elastomer. Gasket materials degrade at varying rates, can be permeated with microorganisms and can entrap soil or microorganisms within coupling seal cavities thus reducing the efficiency of cleaning and sterilization.

NOTE 2 Repeated expansion and contraction of elastomer gaskets due to variable pressures and temperatures can cause deterioration of the elastomer.

5 Performance classes

The coupling shall be classified for leaktightness, cleanability and sterilizability in accordance with 5.1 to 5.4 of EN 13312-1:2001.

The selection of the appropriate class for performance of a coupling shall be made in accordance with 5.5 of EN 13312-1:2001.

6 Classification and verification of performance

6.1 General

The coupling shall conform to the general requirements given in 6.1 of EN 13312-1:2001. Couplings that are an integral part of a unit of equipment, i.e. a vessel with inlet and outlet ports, shall meet the performance requirements for that unit of equipment.

NOTE Standards for hygienic couplings can not guarantee conformance to processes where potentially hazardous microorganisms are used.

References to test methods to test the performance of couplings with regard to leaktightness, cleanability and sterilizability are given in annex A.

6.2 Leaktightness

The coupling shall conform to the requirements given in 6.2 of EN 13312-1:2001.

NOTE Generally couplings are designed to be leaktight to a specified maximum pressure and can be verified by pressure testing when necessary. Pressure testing alone is not proof of leaktightness for microbiological use.

6.3 Cleanability

The coupling shall conform to the requirements given in 6.3 of EN 13312-1:2001.

6.4 Sterilizability

The coupling shall conform to the requirements given in 6.4 of EN 13312-1:2001.

7 Marking and packaging

The coupling shall conform to the requirements given in clause 7 of EN 13312-1:2001.

8 Documentation

The coupling shall conform to the requirements given in clause 8 of EN 13312-1:2001.

Annex A (informative)

Guidance on test methods for determining leaktightness, cleanability and sterilizability of couplings

A.1 Leaktightness

A list of test methods for leaktightness is given in table A.1 of EN 12298 (see [11]). From that list suitable test methods to the testing of couplings are given in table A.1.

Table A.1 - Suitable alternative leaktightness test methods for couplings

Number	Test method
1	Pressure loss - gas/air
2	Pressure loss - liquid
3	Helium probe
4	SF_6, e.g. Freon[a] probe
8	Tracer-liquid dyes
11	Electronic particle counting
12	Tracer aerosol (NaCl)
13	Product aerosol (non-microbial)
14	Qualitative bioaerosol monitoring
15	Quantitative bioaerosol monitoring
16	Surface swabbing
18	Visual inspection (only qualitative)
19	Bacteria tightness
NOTE Restrictive use of SF_6 should be considered due to environment protection	
a Freon is an example of a suitable product available commercially. This information is given for the convenience of the user of this Standard and does not constitute an endorsement of CEN of these products	

A.2 Cleanability

A suitable method for testing cleanability is described in [1].

A.3 Sterilizability

A suitable method for testing sterilizability is described in [2].