



SLOVENSKI STANDARD

SIST EN 13312-4:2002

01-januar-2002

Biotehnologija - Merila za delovanje cevne napeljave in pripomočke - 4. del: Cevi in izvodila

Biotechnology - Performance criteria for piping and instrumentation - Part 4: Tubes and pipes

Biotechnik - Leistungskriterien für Leitungssysteme und Instrumentierung - Teil 4: Rohre und Rohrleitungen

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Biotechnologie - Criteres de performance pour tuyauteries et instrumentation - Partie 4: Tubes et tuyauterie

[SIST EN 13312-4:2002](https://standards.iteh.ai/catalog/standards/sist/055587f8-1951-43aa-9070-0039b604a9b7/sist-en-13312-4-2002)

[https://standards.iteh.ai/catalog/standards/sist/055587f8-1951-43aa-9070-](https://standards.iteh.ai/catalog/standards/sist/055587f8-1951-43aa-9070-0039b604a9b7/sist-en-13312-4-2002)

[0039b604a9b7/sist-en-13312-4-2002](https://standards.iteh.ai/catalog/standards/sist/055587f8-1951-43aa-9070-0039b604a9b7/sist-en-13312-4-2002)

Ta slovenski standard je istoveten z: EN 13312-4:2001

ICS:

07.080	Biologija. Botanika. Zoologija	Biology. Botany. Zoology
23.040.01	Deli cevovodov in cevovodi na splošno	Pipeline components and pipelines in general

SIST EN 13312-4:2002

en

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN 13312-4:2002

<https://standards.iteh.ai/catalog/standards/sist/055587f8-1951-43aa-9070-0039b604a9b7/sist-en-13312-4-2002>

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 13312-4

February 2001

ICS 07.080; 07.100.01

English version

Biotechnology - Performance criteria for piping and instrumentation - Part 4: Tubes and pipes

Biotechnologie - Critères de performance pour tuyauteries et instrumentation - Partie 4: Tubes et tuyauterie

Biotechnik - Leistungskriterien für Leitungssysteme und Instrumentierung - Teil 4: Rohre und Rohrleitungen

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

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

[SIST EN 13312-4:2002](https://standards.iteh.ai/catalog/standards/sist/055587f8-1951-43aa-9070-0039b604a9b7/sist-en-13312-4-2002)

<https://standards.iteh.ai/catalog/standards/sist/055587f8-1951-43aa-9070-0039b604a9b7/sist-en-13312-4-2002>



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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Contents

	Page
Foreword.....	3
Introduction	4
1 Scope.....	4
2 Normative references	4
3 Terms and definitions.....	4
4 Hazards.....	4
5 Performance classes	5
6 Classification and verification of performance.....	5
7 Marking and packaging	6
8 Documentation.....	6
Annex A (informative) Guidance on test methods for determining leaktightness, cleanability and sterilizability of tubes and pipes	7
Annex B (informative) Guidance of design for tubes and pipes.....	8
Bibliography	9

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN 13312-4:2002

<https://standards.iteh.ai/catalog/standards/sist/0555878-1951-43aa-9070-0039b604a9b7/sist-en-13312-4-2002>

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

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

1 Scope

This European Standard specifies performance criteria for tubes and pipes 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 tubes and pipes 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. This European Standard is also applicable to flexible pipes and tubes.

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).

<https://standards.iteh.ai/catalog/standards/sist/055587f8-1951-43aa-9070-003-Performance-criteria-for-piping-and-instrumentation-4-2001>

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 incorrectly welded joints and seams.

NOTE 1 Discontinuities in the internal surface like excessive penetration or undercut can harbour soil and can prevent drainage. Poor welding techniques such as misalignment, lack of adequate removal of oxygen to prevent oxidation during welding, uneven temperature and uneven speed can also result in a variety of surface imperfections and poor weld-penetration and possible leakages.

- b) Release of microorganisms caused by mismatching of tubes and pipes resulting in inappropriate cleaning and therefore inappropriate sterilization.

NOTE 2 Mismatching leads to incorrectly welded joints. This is very likely to occur because there is a multiplicity of internal and external sizes and combinations hereof within existing standards (see [1], [2], [3], [4], [5], [6], [7], [8], [9], [10] and [11]). Furthermore, many of these sizes are very close to each other and cannot be differentiated in existing installation merely by measuring their external diameters.

NOTE 3 Distortion from the original dimensions of tubes and pipes during transport can cause mismatching.

c) Poor installation design resulting in dead-spots and soil-traps, inadequate mechanical support, poor drainage and cold-spots. Poor installation design can in itself reduce the performance classes for cleanability and sterilizability below that which is required.

d) Inadequate materials used, even some types of stainless steel, leading to a variety of corrosion mechanisms, abrasion and chemical attack by process and cleaning materials. Use of these materials can reduce the performance classes for cleanability, leaktightness and sterilizability below that which is required.

e) Release of microorganisms caused by overpressurizing of especially flexible tubes and/or high temperature and/or aggressive media.

f) Release of microorganisms caused by breakage resulting from fatigue and overflexing.

iTeh STANDARD PREVIEW (standards.iteh.ai)

5 Performance classes

The tubes and pipes shall be classified for leaktightness, cleanability and sterilizability in accordance with 5.1 to 5.4 of EN 13312-1:2001:312-4:2002

<https://standards.iteh.ai/catalog/standards/sist/055587f8-1951-43aa-9070->

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

NOTE 1 Leaktightness of tubes and pipes can be obtained by a quality assurance approach to manufacture and installation. In particular, joints should be welded wherever possible and welding practice should be documented. Orbital welding should be used where possible.

NOTE 2 Inspection of welds by boroscopy and radiography can be carried out on a specific percentage of welds. In the event of failures on neighbouring seam welds, all welds in the same weldingrun (man, day) should be examined. Failure of seam welds can be avoided by quality assurance of the supplier, using a quality system in accordance with EN ISO 9001:1994 (see [12]) or equivalent.

6 Classification and verification of performance

Tubes and pipes shall conform to the general requirements given in clause 6 of EN 13312-1:2001. Tubes and pipes that are an integral part of a unit of equipment shall meet the performance requirements for that unit of equipment.

Guidance on test methods for determining leaktightness of tubes and pipes is given in annex A.

Guidance on design for tubes and pipes is given in annex B.

7 Marking and packaging

Tubes and pipes shall conform to the requirements given in clause 7 of EN 13312-1:2001.

8 Documentation

Tubes and pipes shall conform to the requirements given in clause 8 of EN 13312-1:2001.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN 13312-4:2002

<https://standards.iteh.ai/catalog/standards/sist/055587f8-1951-43aa-9070-0039b604a9b7/sist-en-13312-4-2002>

Annex A (informative)**Guidance on test methods for determining leaktightness, cleanability and sterilizability of tubes and pipes**

A list of test methods for leaktightness is given in table A.1 of EN 12298:1998 (see [13]). From that list suitable test methods to the testing of tubes and pipes are given in table A.1.

Table A.1 - Suitable alternative leaktightness test methods for tubes and pipes

Number	Test method
1	Pressure loss - gas/air
2	Pressure loss - liquid
3	Helium probe
4	SF ₆ , e.g. Freon ^a probe
5	Thermal conductivity
6	Ultrasonics
8	Tracer-liquid dyes
12	Tracer aerosol (NaCl)
14	Qualitative bioaerosol monitoring
15	Quantitative bioaerosol monitoring
17	Surface conductivity
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.	