SLOVENSKI STANDARD
SIST EN 13312-6:2002

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Biotehnologija - Merila za delovanje cevne napeljave in pripomočke - 6. del: Sonde

Biotechnology - Performance criteria for piping and instrumentation - Part 6: Equipment probes

Biotechnik - Leistungskriterien für Leitungssysteme und Instrumentierung - Teil 6: Gerätesonden

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Biotechnologie - Criteres de performance pour tuyauteries et instrumentation - Partie 6: Sondes d'instrumentation

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Biotechnology - Performance criteria for piping and instrumentation - Part 6: Equipment probes

Biotechnologie - Critères de performance pour tuyauteries et instrumentation - Partie 6: Sondes d'instrumentation

Biotechnik - Leistungskriterien für Leitungssysteme und Instrumentierung - Teil 6: Gerätesonden

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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Foreword

This draft European Standard has been prepared by the 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of an identical text or by endorsement, at the latest by August 2001, and conflicting national standards shall be withdrawn at the latest by August 2001.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.*

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

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

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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.

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Introduction

Equipment probes are devices used to measure process parameters such as pH, concentration of oxygen, biomass and other substrates and products, temperature, pressure, foam level and conductivity. They are inserted into a piece of equipment through the barrier that encloses the closed system. Therefore probes can be in direct contact with the microorganisms being used in the process.

Usually a measuring system or a measuring chain consists of a equipment probe containing a sensor, a signal transmitter and a signal indicator. The measuring system can be stand-alone or coupled to a monitoring and control system.

The performance criteria cleanability and sterilizability will be influenced by the design of the probe, whereas the criterion leaktightness will be mainly influenced by the way the probe is housed in the equipment.

Use of this European Standard will aid the equipment manufacturer in the classification of equipment probes 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

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

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This European Standard applies where the intended use of the equipment probes 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.

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4 Hazards

The following hazards shall be taken into account.

a) Release of microorganisms caused by non-compatibility of equipment probes and ports.

b) Release of microorganisms caused by deterioration of the gasket.

c) Release of microorganisms caused by improper replacement of gaskets.

d) Release of microorganisms caused by loosening of the equipment probe.

e) Release of microorganisms caused by breakage of the equipment probe.

f) Release of microorganisms caused by transport of microorganisms through the barrier of the closed system if the position of a sliding equipment probe is adjusted.

Hazards mentioned under a), b), c) and d) are discussed in more detail in EN 13312-2 (see [1]) and EN 13312-3 (see [2]).

Although this standard does not apply to the consequences of malfunctioning of the measuring system of which the equipment probe is part, the following shall be taken into account :

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- release of microorganisms can occur caused by malfunctioning of the measuring system, leading to no or incorrect actions based on misinformation ;

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- release of microorganisms when opening or dismantling the equipment caused by inadequate inactivation procedure resulting from malfunctioning of pressure and/or temperature indicators.

5 Performance classes

The equiment probe 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 an equipment probe shall be made in accordance with 5.5 of EN 13312-1:2001.

6 Classification and verification of performance

6.1 General

The equipment probes shall conform to the general requirements given in 6.1 of EN 13312-1:2001.

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6.2 Leaktightness

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

Guidance on test methods for determining leaktightness of equipment is given in annex A.

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

6.3 Cleanability

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

6.4 Sterilizability

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

7 Marking and packaging

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

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8 Documentation

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

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Annex A (informative)

Guidance on test methods for determining leaktightness of equipment probes

A list of test methods for leaktightness is given in table A.1 of EN 12298:1998 (see [3]). From that list suitable test methods to the testing of equipment probes are given in table A.1.

Table A.1 - Suitable alternative leaktightness test methods for equipment probes

Number	Test method
1	Pressure loss - gas/air
2	Pressure loss - liquid
5	Thermal conductivity
11	Electronic particle counting
12	Tracer aerosol (NaCl)
14	Qualitative bioaerosol monitoring
15	Quantitative bioaerosol monitoring

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