SLOVENSKI STANDARD
SIST EN 13312-1:2002

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Biotehnologija - Merila za delovanje cevne napeljave in pripomočke - 1. del: Splošna merila za delovanje

Biotechnology - Performance criteria for piping and instrumentation - Part 1: General performance criteria

Biotechnik - Leistungskriterien für Leitungssysteme und Instrumentierung - Teil 1: Allgemeine Leistungskriterien

Biotechnologie - Criteres de performance pour tuyauteries et instrumentation - Partie 1: Criteres généraux de performance

Ta slovenski standard je istoveten z: **EN 13312-1:2001**

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07.080	Biologija. Botanika. Zoologija	Biology. Botany. Zoology
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Biotechnology - Performance criteria for piping and instrumentation - Part 1: General performance criteria

Biotechnologie - Critères de performance pour tuyauteries et instrumentation - Partie 1: Critères généraux de performance

Biotechnik - Leistungskriterien für Leitungssysteme und Instrumentierung - Teil 1: Allgemeine Leistungskriterien

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.

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

Use of this European Standard will aid the equipment manufacturer in the classification of couplings, sampling and inoculation devices, tubes and pipes, valves and 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

This European Standard specifies performance criteria for piping and instrumentation 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 equipment 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 1672-2, *Food processing machinery - Basic concepts - Part 2: Hygiene requirements.*

EN 12296, *Biotechnology - Equipment - Guidance on testing procedures for cleanability.*

EN 12297, *Biotechnology - Equipment - Guidance on testing procedures for sterilizability.*

EN 12298, *Biotechnology - Equipment - Guidance on testing procedures for leaktightness.*

EN ISO 4287, *Geometrical product specifications (GPS) - Surface texture: Profile method - Terms, definitions and surface texture parameters (ISO 4287:1997).*

EN ISO 4288, *Geometrical Product Specifications (GPS) - Surface texture: Profile method - Rules and procedures for the assessment of surface texture (ISO 4288:1996).*

3 Terms and definitions

For the purposes of this standard, the following terms and definitions apply :

3.1
clean

condition of (a) product, surface, device, gases and/or liquids with residual soil below a defined threshold level.

3.2
cleanability

ability to be made clean.

3.3
cleaning

removal of soil.

3.4
cleaning in place (CIP)

cleaning without dismantling of components of equipment and/or unit of equipment.

3.5
closed system

system where a barrier separates microorganisms or organisms from the environment [EN 1620].

3.6
coupling

device enabling two components of equipment to be assembled and disassembled.

3.7
equipment probe

device inserted into a component of equipment to measure some physical or chemical property of interest for the process.

NOTE Probes can be fixed or removable, e.g. sliding probes.

3.8
hazard

intrinsic property or ability of something (e.g. any agent, equipment, material or process) to cause harm [EN 1620].

NOTE Harm is an injury or damage to health of people and/or to the environment.

3.9
inoculation device

device for adding microorganisms to a process.

3.10
leakage

egress from equipment.

3.11
leaktightness

ability of component of equipment or unit of equipment to limit egress.

3.12
microorganism

any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material [EN 1619].

NOTE For the purposes of this standard, the term microorganism covers the term of biological agent, according to the Directive 90/679/EEC : microorganisms, including those which have been genetically modified, cell cultures and human endoparasites which may be able to provoke any infection, allergy or toxicity.

3.13
process microorganism

microorganism used for production purposes in a biotechnological process or constituting (part of) the product itself.

3.14
risk

combination of the probability and the degree of the possible injury or damage to health in a hazardous situation [EN 1070].

3.15
sampling device

device for taking samples from component of equipment and/or unit of equipment.

3.16
soil

any unwanted matter (including product residues, microorganisms, dust and debris) [ISO/DIS 14159:1999].

3.17
sterile

state of being free from viable microorganisms.

NOTE 1 In practice no such absolute statement regarding the absence of viable microorganisms can be proven. However, sterile conditions can be regarded as established by using an accepted or recognized method of sterilization.

NOTE 2 The process of inactivation of viable microorganisms during a sterilization procedure is usually described by an empirical mathematical function, commonly an exponential function. By their mathematical nature, such functions can be reduced to very low numbers, but not to zero. However, these empirical functions can be applied to control or assess the process parameters of a sterilization procedure to realize a desired degree of inactivation of viable microorganisms.

3.18
sterilizability

ability of components of equipment, units of equipment or process plants to be made sterile.

3.19
sterilization

process used to reach a sterile state.

3.20
sterilizing In Place (SIP)

sterilization without opening or dismantling of components of equipment and/or unit of equipment.