SLOVENSKI STANDARD
SIST EN 12462:1999

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Biotehnologija - Merila za delovanje za ļ rpalke

Biotechnology - Performance criteria for pumps

Biotechnik - Leistungskriterien für Pumpen

Biotechnologie - Criteres de performance pour les pompes

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English version

Biotechnology - Performance criteria for pumps

Biotechnologie - Critères de performance pour les pompes

Biotechnik - Leistungskriterien für Pumpen

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

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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of an identical text or by endorsement, at the latest by January 1999, and conflicting national standards shall be withdrawn at the latest by January 1999.

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

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

The mechanical safety of pumps, which are widely used in biotechnological processes, is covered by EN 292-1 and EN 292-2. However, it is important to consider the performance of pumps used in these processes with regard to the potential hazard posed by the microorganism in use. For some microorganisms additional technology is needed to prevent their release to the environment. Consideration should be given to workers, the environment and the public in general.

Use of this standard can facilitate the specification with regard to biosafety performance of pumps by the manufacturer in a form which can be easily understood and readily utilized by the end user.

1 Scope

This European Standard specifies performance criteria for pumps used in biotechnological processes, in which the release of microorganisms should be limited or prevented for reasons of safety.

This standard applies if the intended use of the pump includes hazardous or potentially hazardous microorganisms.

This standard applies to pumps with no auxiliary equipment, bordered by the connections on the unit of equipment. It also applies to pump systems equipped with all necessary auxiliary equipment necessary for operation of pumps and to accomplish cleaning and sterilization.

NOTE : Additional criteria for individual components of equipment such as pipes and couplings are given in "Performance criteria for piping and instrumentation - Part 1 : General performance criteria" (see annex A [9]) and "Performance criteria for piping and instrumentation - Part 2 : Couplings" (see annex A [7]). These two European Standards are being prepared.

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.

EN 285	Sterilization - Steam sterilizers - Large sterilizers
EN 292-1	Safety of machinery - Basic concepts, general principles for design - Part 1 : Basic terminology, methodology
EN 292-2	Safety of machinery - Basic concepts, general principles for design - Part 2 : Technical principles and specifications
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

ISO 4287 Geometrical Product Specifications (GPS) - Surface texture : Profile method - Terms, definitions and surface texture parameters.

EN ISO 4288 Geometrical Product Specifications (GPS) - Surface texture: Profile method - Rules and Procedures for the assessment of surface texture

3 Definitions

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

3.1 arithmetical mean deviation of the profile (R_a)

The arithmetical mean of the absolute values of the profile departures within the sampling length [ISO 4287].

3.2 clean

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

3.3 cleanability

Ability to be made clean.

3.4 cleaning in place (CIP)

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

3.5 component of equipment

Technical entity which forms part of a unit of equipment.

NOTE : Examples of components of equipment are vessels, valves and sensors.

3.6 hazard

Intrinsic potential 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 the environment.

3.7 leakage

Egress from equipment.

3.8 leaktightness

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

3.9 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.

3.10 process microorganism

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

3.11 pump

Item of equipment used for moving liquids through pipes.

NOTE : The liquids may contain gases and/or solids.

3.12 residual soil

Soil left after cleaning.

3.13 risk

Probability of occurrence of a hazard causing harm and the degree of severity of the harm.

3.14 soil

Any unwanted matter (including product residues, microorganisms, dust and debris) [ISO/CD 14159].

3.15 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 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.

3.16 sterilizability

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

3.17 sterilization

Process used to reach a sterile state.

3.18 target microorganism

Process microorganism and/or other microorganisms relevant for a specific process.

NOTE: For safety testing procedures, non-pathogenic microorganisms should be used where possible.

3.19 unit of equipment

Assembly of components used to perform one or more unit operations.

4 Hazards

The following hazards shall be considered :

- release of microorganisms by leakage from a pump during operation ;

- release of microorganisms after operation due to insufficient inactivation and/or removal of microorganisms when the pump is opened or dismantled.

5 Performance classes

5.1 General

With regard to the contained use of microorganisms in pumps, the pump shall be classified for the following performance criteria :

- leaktightness ;

- cleanability ;