SLOVENSKI STANDARD
SIST EN 12690:1999

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Biotehnologija – Merila za delovanje tesnil za gredi

Biotechnology - Performance criteria for shaft seals

Biotechnik - Leistungskriterien für Wellendichtungen

Biotechnologie - Criteres de performance pour les dispositifs d'étanchéité dynamique d'arbre

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English version

Biotechnology - Performance criteria for shaft seals

Biotechnologie - Critères de performance pour les dispositifs d'étanchéité dynamique d'arbre

Biotechnik - Leistungskriterien für Wellendichtungen

This European Standard was approved by CEN on 28 January 1999.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

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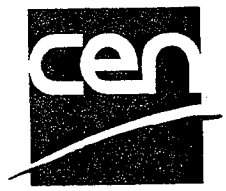

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

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of an identical text or by endorsement, at the latest by August 1999, and conflicting national standards shall be withdrawn at the latest by August 1999.

This draft 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 main function of a seal is to prevent either the escape of product or the ingress of contaminating material depending on the particular application. Undemanding duties can be served by single seals but double seals with a barrier fluid between the primary and secondary seal can be necessary for more stringent applications such as pumps, agitators, centrifuges and homogenizers.

Use of this European Standard will aid the equipment manufacturer in the classification with regard to biosafety performance of shaft seals 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 shaft seals in equipment used in biotechnological processes with respect to the potential risks of microorganisms in use for the worker or the environment.

This European Standard applies where the intended use of the shaft seal includes hazardous or potentially hazardous microorganisms used in biotechnological processes or where exposure of the worker and/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.

EN 285	Sterilization - Steam sterilizers - Large sterilizers
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 12460	Biotechnology - Large-scale process and production - Guidance on equipment selection and installation in accordance with the biological risk
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 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 barrier fluid

Fluid between two seals.

3.3 clean

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

3.4 cleanability

Ability to be made clean.

3.5 dynamic seal

Seal installed between a stationary and a moving element.

3.6 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.

3.7 leakage

Egress from equipment.

3.8 leaktightness

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

3.9 mechanical seal

Seal consisting of two plane faces arranged perpendicular to the axis of a moving shaft.

3.10 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.

3.11 primary seal

Seal between barrier fluid and the process.

3.12 process microorganism

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

3.13 pump

Item of equipment for moving liquids through pipes.

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

3.14 residual soil

Soil left after cleaning.

3.15 risk

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

3.16 rotational shaft

Shaft that rotates around its axis.

3.17 seal

Component installed between a moving and stationary element or between two stationary elements.

NOTE : A seal can consist of one or more sealing elements between the stationary and moving elements and can contain pressurized, sterile fluid between these elements.

3.18 secondary seal

Seal between barrier fluid and a region not contaminated by the process.

3.19 soil

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

3.20 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.

3.21 sterilizability

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

3.22 sterilization

Process used to reach a sterile state.

3.23 target microorganism

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

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

4 Hazards

The following hazards shall be taken into account :