SLOVENSKI STANDARD
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Biotehnologija – Merila za delovaje centrifug

Biotechnology - Performance criteria for centrifuges

Biotechnik - Leistungskriterien für Zentrifugen

Biotechnologie - Criteres de performance pour les centrifugeuses

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English version

Biotechnology - Performance criteria for centrifuges

Biotechnologie - Critères de performance pour les centrifugeuses

Biotechnik - Leistungskriterien für Zentrifugen

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

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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 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

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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of an identical text or by endorsement, at the latest by August 1999, and conflicting national standards shall be withdrawn at the latest by August 1999.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 general safety of centrifuges used in biotechnological processes is covered by EN 292-1, EN 292-2, EN 12547 and EN 61010-2-020 (see annex A [5]). The requirements regarding biosafety for laboratory centrifuges given in EN 61010-2-020 are not in conflict with this European Standard and can be classified into the classes defined here.

For safety reasons it is necessary to consider the performance with respect to leaktightness, cleanability and sterilizability of equipment to be used for biotechnology operations. The actual performance demands will be dependent on the potential hazards to the workers, the environment and the general public of the microorganisms in use. If the performance is known or expected to be insufficient, additional technology may be needed to reach the desired containment level.

Use of this European Standard will aid the equipment manufacturer in the classification with regard to biosafety performance of centrifuges 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 centrifuges 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 centrifuges includes hazardous or potentially hazardous microorganisms used in biotechnological processes and/or where exposure of the worker or the environment to such microorganisms is restricted for reasons of safety.

This European Standard applies to centrifuges with no auxiliary equipment. It also applies to centrifuge systems equipped with all necessary auxiliary equipment for example valves, probes, filters and steam traps, necessary for operation of centrifuges and to accomplish cleaning and sterilization.

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 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 626-1	Safety of machinery - Reduction of risks to health from hazardous substances emitted by machinery - Part 1 : Principles and specifications for machinery manufacturers

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 12547	Centrifuges - Common safety requirements
EN 12690	Biotechnology - Performance criteria for shaft seals
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 casing

Enclosure in which at least the drum rotates and which may constrain process materials leaving the drum to particular paths [EN 12547].

NOTE : The casing may consist of several components.

3.2 centrifuge

Separation device which has a rotatable chamber in which a mixture of process materials can be subjected to (radial) acceleration force.

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 cleaning

Removal of soil.

3.6 cleaning in place (CIP)

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

3.7 closed system

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

3.8 drum

Chamber which holds the process material, and is arranged to rotate about its symmetrical axis [EN 12547].

3.9 gauge pressure

Pressure difference from atmospheric pressure.

3.10 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 the environment.

3.11 leakage

Egress from equipment.

3.12 leaktightness

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

3.13 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.

3.14 risk

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

3.15 rotor

Assembled part of a centrifuge which rotates, comprising drum and shaft together with their attachments [EN 12547].

3.16 soil

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

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.