EESTI STANDARD EVS-EN 12462:1999

Biotehnoloogia. Ekspluatatsioonikriteeriumid pumpadele

Biotechnology - Performance criteria for pumps

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 12462:1999 sisaldab Euroopa standardi EN 12462:1998 ingliskeelset teksti. Käesolev dokument on jõustatud 12.12.1999 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 12462:1999 consists of the English text of the European standard EN 12462:1998. This document is endorsed on 12.12.1999 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: Käesolev Euroopa standard määrab kindlaks ekspluatatsioonikriteeriumid pumpadele, mida kasutatakse biotehnoloogilistes protsessides ning millest mikroorganismide vabadusse pääsemine peaks ohutuse tagamiseks olema piiratud või välditud.	**Scope:**

ICS 07.080

Võtmesõnad: biotehnoloogia, ekspluatatsiooninõuded, hermeetilisus, keskkonnakaitse, laborivarustus, mikroorganismid, ohud, puhastamine, pumbad, saastumine, tehnilised andmed, transgeensed mikroorganismid, tööohutus, õnnetuste vältimine

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Descriptors: Biotechnology, pumps, performance criteria.

English version

Biotechnology

Performance criteria for pumps

Biotechnologie – Critères de performance pour les pompes

Biotechnik – Leistungskriterien für Pumpen

This European Standard was approved by CEN on 1998-07-01.

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.

The European Standards exist 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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CEN

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 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.