Biotechnology - Performance criteria for filter elements and filtration assemblies

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EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN 13091:2000 sisaldab Euroopa standardi EN 13091:1999 ingliskeelset teksti. Käesolev dokument on jõustatud 16.06.2000 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 13091:2000 consists of the English text of the European standard EN 13091:1999. This document is endorsed on 16.06.2000 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This standard specifies performance criteria for filter elements and filtration equipment with respect to the potential risks to the worker and the environment from microorganisms in use.	**Scope:** This standard specifies performance criteria for filter elements and filtration equipment with respect to the potential risks to the worker and the environment from microorganisms in use.

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Võtmesõnad:

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English version

Biotechnology – Performance criteria for filter elements and filtration assemblies

Biotechnologie – Critères de performance pour les éléments filtrants et les filtres

Biotechnik – Leistungskriterien für Filterelemente und Filtrationseinrichtungen

This European Standard was approved by CEN on 1999-09-25.

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.

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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 June 2000, and conflicting national standards shall be withdrawn at the latest by June 2000.

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

Filter elements by nature are not intended to prevent the passage of fluids, but to remove or reduce the microorganism load to acceptable levels, by retention of the target microorganisms within the filter medium. Leaktightness in this context refers to the ability of the filtration assembly to retain the target microorganism.

Use of this European Standard will aid the equipment manufacturer in the classification of filter elements and filtration assemblies with regard to biosafety performance in biotechnological processes. The classification is easily understandable and readily utilizable for the user and the competent authorities.

1 Scope

This European Standard specifies performance criteria for filter elements and filtration assemblies used in biotechnological processes with respect to the potential risks of microorganisms in use for the worker and the environment.

This European Standard applies where the intended use of the filter elements or filtration assemblies 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 sterilizability and cleanability of filter assemblies and to leakage of microorganisms through the housing of a filtration assembly and to leakage of microorganisms through filter elements for dead-end filtration and cross-flow filtration.

This European Standard does not apply to filter elements and filtration assemblies used to avoid contamination of bioreactors for example by sterilizing inlet air or feedstream.

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 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 Terms and 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 [EN ISO 4287].

3.2
cartridge

disposable filter element.

3.3
cross-flow filtration

filtration characterized by a flow alongside the filter medium surface (retentate) and a flow crossing the filter medium (permeate).

NOTE Examples of cross-flow filtration are reversed osmosis, dialysis, microfiltration, ultrafiltration and nanofiltration.

3.4
cut-off

smallest particle size or molecular weight components retained at a given reduction efficiency.

3.5
dead-end filtration

filtration characterized by a feed forced through the filter medium depositing retentate in or on the filter medium.