

# Biotechnology — Performance criteria for filter elements and filtration assemblies

The European Standard EN 13091:1999 has the status of a  
British Standard

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# National foreword

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- present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

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## Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 19 and a back cover.

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This British Standard, having been prepared under the direction of the Sector Committee for Materials and Chemicals, was published under the authority of the Standards Committee and comes into effect on 15 March 2000

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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 25 September 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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## 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of an identical text or by endorsement, at the latest by May 2000, and conflicting national standards shall be withdrawn at the latest by May 2000.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

NOTE Examples of dead-end filtration are filtration by means of sand filters, wound cartridges, high efficiency particulate air (HEPA) filters, sintered glass filters and sterilizing membrane cartridges.