Biotechnology - Performance criteria for vessels - Part 4: Bioreactors

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EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 13311-4:2001 sisaldab Euroopa standardi EN 13311-4:2001 ingliskeelset teksti. Käesolev dokument on jõustatud 16.11.2001 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 13311-4:2001 consists of the English text of the European standard EN 13311-4:2001. This document is endorsed on 16.11.2001 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 European Standard specifies performance criteria for bioreactors used in biotechnological processes with respect to the potential hazards to the worker and the environment from microorganisms in use.	**Scope:** This European Standard specifies performance criteria for bioreactors used in biotechnological processes with respect to the potential hazards to the worker and the environment from microorganisms in use.

ICS 07.080, 07.100.01

Võtmesõnad: classifications, environme, equipment, hazards, leakage, management, microbiology, microorganims, microorganisms, micro-organisms, performance, pollution control, pressure-tight, protection devices, safety, safety requirements, specification (approval), specifications

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 13311-4

March 2001

ICS 07.080; 07.100.01

English version

Biotechnology - Performance criteria for vessels - Part 4: Bioreactors

Biotechnologie - Critères de performance des récipients - Partie 4: Bioréacteurs

Biotechnik - Leistungskriterien für Behälter - Teil 4: Bioreaktoren

This European Standard was approved by CEN on 4 February 2001.

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 Management Centre 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
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Ref. No. EN 13311-4:2001 E

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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 September 2001, and conflicting national standards shall be withdrawn at the latest by September 2001.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

This standard is one of a series of European Standards concerned with performance criteria for vessels. These standards are:

EN 13311-1, *Biotechnology - Performance criteria for vessels - Part 1: General performance criteria.*

EN 13311-2, *Biotechnology - Performance criteria for vessels - Part 2: Pressure protection devices.*

EN 13311-3, *Biotechnology - Performance criteria for vessels - Part 3: Glass pressure vessels.*

EN 13311-4, *Biotechnology - Performance criteria for vessels - Part 4: Bioreactors.*

EN 13311-5, *Biotechnology - Performance criteria for vessels - Part 5: Kill tanks.*

EN 13311-6, *Biotechnology - Performance criteria for vessels - Part 6: Chromatography columns.*

Annexes A and B are informative.

This standard includes a bibliography.

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

Use of this European Standard will aid the equipment manufacturer in the classification of bioreactors with regard to safe performance 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 bioreactors used in biotechnological processes with respect to the potential hazards to the worker and the environment from microorganisms in use.

This European Standard applies where the intended use of bioreactors includes hazardous or potentially hazardous microorganisms used in biotechnological processes or where exposure of the worker 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 (including amendments).

EN 13311-1:2001	Biotechnology - Performance criteria for vessels - Part 1 : General performance criteria

3 Terms and definitions

For the purposes of this standard, the terms and definitions given in EN 13311-1:2001 apply.

4 Hazards

Typical examples for potential hazards of bioreactors and recommendations for proper design and handling are included in annex B.

5 Performance classes

The bioreactors shall be classified for leaktightness, cleanability and sterilizability in accordance with 5.1 to 5.4 of EN 13311-1:2001.

The selection of the appropriate class for performance of a bioreactor shall be made in accordance with 5.5 of EN 13311-1:2001.