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**BIOTECHNOLOGY - PERFORMANCE
CRITERIA FOR SHAFT SEALS**

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English version

Biotechnology - Performance criteria for shaft seals

Biotechnologie - Critères de performance pour les dispositifs d'étanchéité dynamique d'arbre

Biotechnik - Leistungskriterien für Wellendichtungen

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

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.

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.

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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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of an identical text or by endorsement, at the latest by August 1999, and conflicting national standards shall be withdrawn at the latest by August 1999.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 main function of a seal is to prevent either the escape of product or the ingress of contaminating material depending on the particular application. Undemanding duties can be served by single seals but double seals with a barrier fluid between the primary and secondary seal can be necessary for more stringent applications such as pumps, agitators, centrifuges and homogenizers.

Use of this European Standard will aid the equipment manufacturer in the classification with regard to biosafety performance of shaft seals 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 shaft seals in equipment 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 shaft seal includes hazardous or potentially hazardous microorganisms used in biotechnological processes or where exposure of the worker and/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.

EN 285	Sterilization - Steam sterilizers - Large sterilizers
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)

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