

**Biotehnoloogia.
Ekspluatatsioonikriteeriumid
aurusterilisaatoritele ja autoklaavidele**

Biotechnology - Performance criteria for steam
sterilizers and autoclaves

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN 12347:1999 sisaldab Euroopa standardi EN 12347:1998 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 12.12.1999 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN 12347:1999 consists of the English text of the European standard EN 12347:1998.</p> <p>This document is endorsed on 12.12.1999 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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<p>Käsitlusala:</p> <p>Käesolev Euroopa standard määrab kindlaks ekspluatatsioonikriteeriumid aurusterilisaatoritele ja autoklaavidele, mis on ette nähtud biotehnoloogilistes protsessides kasutatavate mikroorganismide hävitamiseks ning vabadusse pääsemise ärahoidmiseks.</p>	<p>Scope:</p>
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ICS 07.080

Võtmesõnad: autoklaavid, biotehnoloogia, definitsioonid, hermeetilisus, iseloomulikud tunnused, kahjulikud mikroorganismid, klassifikatsioonid, mikroorganismid, ohud, puhastamine, steriliseerimine, tehnilised andmed, tõendamine, õnnetuste vältimine

ICS 07.080; 07.100.99; 11.080

Descriptors: Biotechnology, steam sterilizers, autoclaves, performance criteria.

English version

Biotechnology

**Performance criteria for steam sterilizers and
autoclaves**

Biotechnologie – Critères de performance pour les stérilisateurs à la vapeur d'eau et les autoclaves

Biotechnik – Leistungskriterien für Dampf-Sterilisatoren und Autoklaven

This European Standard was approved by CEN on 1998-02-15.

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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

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Contents	Page
Foreword	2
Introduction	3
1 Scope	3
2 Normative references	3
3 Definitions	4
4 Hazards	6
5 Performance classification	6
6 Classification of steam sterilizers and autoclaves	8
7 Verification of performance	9
8 Marking and packaging	10
9 Documents	11
Annex A (informative) Bibliography	11

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

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 1998, and conflicting national standards shall be withdrawn at the latest by September 1998.

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

Steam sterilizers and autoclaves are used to destroy microorganisms by subjecting them to steam (steam sterilizers) or to steam at elevated temperatures and pressure (autoclaves). They are for example used for :

- sterilizing materials and units of equipment before they are used in laboratories or/and factories ;
- eliminating the risk associated with material which requires inactivation and/or sterilization prior to disposal in waste treatment operations ;
- making equipment safe for (re)use.

It is important to consider the performance of steam sterilizers and autoclaves used for these purposes with regard to the potential hazard posed by the microorganism in use. For some microorganisms additional measures are needed to prevent their release from the autoclave before or after sterilization and to treat exhaust gases and/or condensates which can be released during or after the process. Consideration should be given to workers, the environment and the public in general. See also EN 285 for general requirements for large steam sterilizers and autoclaves.

1 Scope

This European Standard specifies performance criteria for the steam sterilizer and autoclave used for the destruction and prevention of release of microorganisms used in biotechnological processes.

This European Standard applies if the intended use of steam sterilizers or autoclaves includes hazardous or potentially hazardous microorganisms used in biotechnological processes or if exposure of the worker or the environment to such microorganisms is restricted for reasons of safety.

Additional criteria for individual components of a steam sterilizer or autoclave such as filters, couplings, pipes are given in European standards on biotechnology pertaining to performance criteria for filter elements, filtration equipment, tubes and pipes and couplings being prepared.

2 Normative references

This European Standard incorporates by dated or undated references, 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 554	Sterilization of medical devices - Validation and routine control of sterilization by moist heat
EN 866-1	Biological systems for testing sterilizers and sterilization processes - Part 1 : General requirements

EN 866-3	Biological systems for testing sterilizers and sterilization processes - Part 3 : Particular systems for use in moist heat sterilizers
prEN 866-7	Biological systems for testing sterilizers and sterilization processes - Part 7 : Particular requirements for self-contained biological indicator systems for use in moist heat sterilizers
EN 867-1	Non-biological systems for use in sterilizers - Part 1 : General requirements
EN 867-2	Non-biological systems for use in sterilizers - Part 2 : Process indicators (Class A)
EN 1619	Biotechnology - Large-scale process and production - General requirements for management and organization for strain conservation procedures
EN 1620	Biotechnology - Large-scale process and production - Plant building according to the degree of hazard
EN 1672-2	Food processing machinery - Safety and hygiene requirements - Basic concepts - Part 2 : Hygiene requirements
prEN 12296	Biotechnology - Equipment - Guidance for testing procedures for cleanability
prEN 12297	Biotechnology - Equipment - Guidance for testing procedures for sterilizability
prEN 12298	Biotechnology - Equipment - Guidance for testing procedures for leaktightness
ISO 4287-1	Surface roughness - Terminology - Part 1 : Surface and its parameters
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 autoclave

Apparatus designed to sterilize materials and/or equipment by exposure to steam at a pressure above the atmospheric pressure.

3.2 cleanability

Ability to be made clean.