SLOVENSKI STANDARD
SIST EN 12347:1999

01-december-1999

Biotehnologija – Merila za delovanje parnih sterilizatorjev in avtoklavov

Biotechnology - Performance criteria for steam sterilizers and autoclaves

Biotechnik - Leistungskriterien für Dampf-Sterilisatoren und Autoklaven

Biotechnologie - Criteres de performance pour les stérilisateurs a la vapeur d'eau et les autoclaves

Ta slovenski standard je istoveten z: **EN 12347:1998**

ICS:

07.080	Biologija. Botanika. Zoologija	Biology. Botany. Zoology
11.080.10	Sterilizacijska oprema	Sterilizing equipment

SIST EN 12347:1999 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 12347

March 1998

ICS 07.080; 07.100.99; 11.080

Descriptors: biotechnology, autoclaves, micro-organisms, noxious micro-organisms, accident prevention, hazards, definitions, characteristics, leaktightness, cleaning, sterilization, classifications, specifications, verification

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

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN 12347:1998 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 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of an identical text or by endorsement, at the latest by September 1998, and conflicting national standards shall be withdrawn at the latest by September 1998.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 builiding 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.

3.3 hazard

Intrinsic property or ability of something (e.g. any agent, equipment, material or process) to cause harm [EN 1620].

NOTE : Harm is an injury or damage to health of people and/or the environment.

3.4 leakage

Egress from equipment.

3.5 leaktightness

Ability of component of equipment or unit of equipment to limit egress.

3.6 microorganism

Any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material [EN 1619].

NOTE : For the purposes of this standard, the term microorganism covers the term of biological agent according to the Directive 90/679/EEC : microorganisms, including those which have been genetically modified, cell cultures and human endoparasites which can provoke any infection, allergy or toxicity.

3.7 risk

Probability of occurrence of a hazard causing harm and the degree of severity of the harm.

3.8 steam sterilizer

Apparatus designed to sterilize materials and/or equipment by exposure to steam.

3.9 sterile

State of being free from viable microorganisms.

NOTE 1 : In practice no such absolute statement regarding the absence of viable microorganisms can be proven. However, sterile conditions can be regarded as established by using an accepted or recognized method of sterilization.

NOTE 2 : The process of inactivation of viable microorganisms during a sterilization procedure is usually described by an empirical mathematical function, commonly an exponential function. By their mathematical nature, such functions can be reduced to very low numbers, but not to zero. However, these empirical functions can be applied to control or assess the process parameters of a sterilization procedure to realize a desired degree of inactivation of viable microorganisms.

3.10 sterilizability

Ability of components of equipment, units of equipment or plants to be sterilized.

3.11 sterilization

Process used to reach a sterile state.

3.12 target microorganism

Process microorganism and/or other microorganisms relevant for the specific process.

NOTE : For safety testing procedures, non-pathogenic microorganisms should be used where possible.

4 Hazards

The following hazards shall be considered :

- release of microorganisms after operation due to insufficient inactivation and/or removal of microorganisms when the equipment is opened or dismantled ;
- release of microorganisms by leakage during or after operation ;
- release of microorganisms by exhaust gases or condensate.

5 Performance classification

5.1 General

With regard to the contained use of microorganisms in the steam sterilizer or autoclave, the steam sterilizer or autoclave shall be classified for the following performance criteria :

- leaktightness ;
- cleanability ;
- sterilizability.

The performance of the steam sterilizer or autoclave shall be determined for each of these criteria. The equipment shall be classified in accordance with tables 1, 2 and 3. For each criterion the equipment shall be classified independently.

NOTE : Equipment can for example be in class SI-A for sterilizability, but in class LI-C for leaktightness.

5.2 Leaktightness

The performance class for leaktightness of the steam sterilizer or autoclave shall be determined in accordance with table 1.