Biotehnoloogia. Aparatuur. Juhend steriilsuse kontrollimise protseduurideks

Biotechnology - Equipment - Guidance on testing procedures for sterilizability

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN 12297:1999 sisaldab Euroopa standardi EN 12297:1998 ingliskeelset teksti. Käesolev dokument on jõustatud 12.12.1999 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 12297:1999 consists of the English text of the European standard EN 12297:1998. This document is endorsed on 12.12.1999 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: Käesolev Euroopa standard annab juhendi biotehnoloogilistes protsessides kasutatava aparatuuri (üksikaparaatide ja nende osade) steriilsuse hindamise üldisteks protseduurideks.	**Scope:**

ICS 07.080

Võtmesõnad: biotehnoloogia, desinfitseerimine, hügieeninõuded, kahjulikud mikroorganismid, keskkonnakaitse, kontroll, meditsiiniaparatuur, mikroorganismid, ohutus, saastumine, steriliseerimine, testimine, tööohutus, õnnetuste vältimine

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Descriptors: Biotechnology, sterilizability, medical equipment, testing.

English version

Biotechnology – Equipment
Guidance on testing procedures for sterilizability

Biotechnologie – Equipement – Guide des procédures d'essai pour le contrôle de la capacité à la stérilisation

Biotechnik – Geräte und Ausrüstungen – Leitfaden für Verfahren zur Prüfung der Sterilisierbarkeit

This European Standard was approved by CEN on 1998-03-02.

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.

The European Standards exist 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, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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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 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.

1 Scope

This European Standard gives guidance on general testing procedures to assess the sterilizability for microorganisms of equipment (components and units of equipment) used in biotechnological processes.

This European Standard gives guidance on the assessment of the sterilizability of biotechnological equipment with respect to a release of process microorganisms that can affect the safety of the worker (occupational health) and/or that can have adverse effects to the environment.

This European Standard is applicable to plants or components, such as valves and fittings, tanks, pumps, piping, separating and filling devices as well as instrumentation in contact with process fluids.

This European Standard applies if the intended use of the equipment includes hazardous or potentially hazardous microorganisms.

This European Standard is not applicable to testing for sterility of media and equipment prior to processing or operation, respectively.

NOTE 1 : For disinfection of external surfaces such as walls, working benches and floors, attention is drawn to national and European Standards.

NOTE 2 : For sterilization of equipment and media in autoclaves attention is drawn to national and European standards such as EN 285 and EN 554 (see annex C [21], [22]).

2 Definitions

For the purposes of this standard, the following definitions apply :

2.1 component of equipment

Technical entity which forms part of a unit of equipment.