EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
EN 285:2006

prA1

July 2006

ICS

English Version

Sterilization - Steam sterilizers - Large sterilizers

Stérilisation - Stérilisateurs à la vapeur d'eau - Grands stérilisateurs

Sterilisation - Dampf-Sterilisatoren - Groß-Sterilisatoren

This draft amendment is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 102.

This draft amendment A1, if approved, will modify the European Standard EN 285:2006. If this draft becomes an amendment, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration.

This draft amendment was established by CEN 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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN 285:2006/prA1:2006: E

Contents

Page

Foreword

This document (EN 285:2006/prA1:2006) has been prepared by Technical Committee CEN/TC 102 “Sterilizers for medical purposes”, the secretariat of which is held by DIN.

This document is currently submitted to the CEN Enquiry.

Revised text

2 Clause

Add

EN 867-5, *Non-biological systems for use in sterilizers – Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers type B and type S*

7.1.13

Delete at the end of the first sentence "(e.g. the sterilization of instruments, textiles, rubber)"

8.1.3

replace the text of "NOTE 2" by the following

"NOTE 2 In healthcare there has been an increase in the use of instruments with long lumens. For some of these instruments the dilution efficacy identified by the tests based on textile loads may be inadequate. These tests have their origin in the steam penetration test using a textile pack[2] conceived during a period when products processed routinely in healthcare were predominantly textile. It was designed to establish that at the commencement of the plateau period, air dilution had been sufficient to achieve a vapour temperature throughout a textile load equivalent to the vapour pressure of the steam in the sterilizer chamber. The hollow load test compliments these tests and should be regarded as an addition to, and not as a replacement to them. A successful hollow load test indicates adequate air dilution and even steam penetration into a process challenge device. A failure of any steam penetration test can be caused by an inefficient air removal stage, the presence of an air leak into the sterilizer chamber, and/or the presence of non-condensable gases in the steam supply."

Add a new subclause

8.1.4 When tested in accordance with Clause 15, the result shall be in accordance with 8.3.5.

Add a new subclause

8.3.5 Hollow load test

When the sterilizer is tested in accordance with Clause 15, the indicator system shall have reached its defined endpoint as described by the manufacturer of the indicator system.

14.1.1

Table 4

Delete the 1st line of Table 4 completely.

Add under air removal and steam penetration:

- hollow load test, requirement according to: 8.3.5; test according to: 15; Type test (see Annex F): X;

14.3

add under l): "hollow load test"

Delete item j).

Replace Clause 15 by the following text:

15 Hollow load test

15.1 General

The hollow load test is used to demonstrate that at the levels at which the controls are set, air dilution from within the test piece is sufficient to permit even steam penetration into it.

15.2 Apparatus

15.2.1 One hollow load process challenge device as described in 24.8, and preconditioned such that the internal environment within the lumen and capsule are at a temperature of between 20 °C and 30 °C and a relative humidity between 40 % and 60 %.

NOTE Residual moisture from previous use, trapped within the hollow load process challenge device will have a deleterious effect on the test results.

15.2.2 Hollow load process challenge device and indicator system in accordance with EN 867-5 .

15.2.3 Connected services complying with clause 13.

15.3 Procedure

15.3.1 Select the sterilization cycle to be tested (see 7.1.13). Ensure the plateau period is within the time and temperature exposure limits specified for the indicator system identified in 15.2.2.

15.3.2 Carry out a sterilization cycle with the sterilizer chamber empty and without any extended drying time.

NOTE This cycle may be omitted if data is available to demonstrate that conditioning by the previous cycle has a similar effect.

15.3.3 Open the capsule of the hollow load process challenge device and then following the manufacturer's instructions, confirm;

a) liquid water is not visually present;

b) the seal and its mating surfaces are satisfactory.

15.3.4 Following the manufacturer's instructions, insert into the capsule an indicator system (15.2.2) and then replace the seal and cap.

15.3.5 Place the hollow load test pack above the nominal geometric centre of the horizontal plane of the usable space supported between 100 mm and 200 mm above the chamber base.

15.3.6 Carry out a sterilization cycle in accordance with the manufacturers operating procedure.

15.3.7 At the end of the test examine the indicator system for compliance with the requirements specified in 8.3.5.

15.3.8 Dispose the used indicator systems in accordance with the manufacturer's instructions.

Delete 24.8 completely

26.3

List item b), 2nd dash:

delete the wording in brackets "(e.g. porous load, metal load, rubber load); kind of packing)"

Annex E

Table E.1

Amend Table E.1 as follows:

Replace the line "miobiological test, rubber" by the following:

hollow load test, requirement according to 8.3.5, test according to 15, Installation Qualification: -; Operational Qualification: XX .

Annex F

F.1

In the last paragraph, fist sentence, replace "rubber" by “hollow”