SLOVENSKI STANDARD
SIST EN 552:2000/A1:2000

01-januar-2000

Sterilizacija medicinskih pripomoļ kov - Validacija in redni nadzor sterilizacije z obsevanjem

Sterilization of medical devices - Validation and routine control of sterilization by irradiation

Sterilisation von Medizinprodukten - Validierung und Routineüberwachung für die Sterilisation mit Strahlen

Stérilisation de dispositifs médicaux - Validation et contrôle de routine pour la stérilisation par irradiation

Ta slovenski standard je istoveten z: **EN 552:1994/A1:1999**

ICS:

11.080.01	Sterilizacija in dezinfekcija na splošno	Sterilization and disinfection in general

SIST EN 552:2000/A1:2000 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 552:1994/A1

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English version

Sterilization of medical devices - Validation and routine control of sterilization by irradiation

Stérilisation de dispositifs médicaux - Validation et contrôle de routine pour la stérilisation par irradiation

Sterilisation von Medizinprodukten - Validierung und Routineüberwachung für die Sterilisation mit Strahlen

This amendment A1 modifies the European Standard EN 552:1994; it was approved by CEN on 16 April 1999.

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. 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 amendment 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
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This Amendment EN 552:1994/A1:1999 to EN 552:1994 has been prepared by Technical Committee CEN/TC 204 "Sterilization of medical devices", the secretariat of which is held by BSI.

This Amendment to the European Standard EN 552:1994 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 1999, and conflicting national standards shall be withdrawn at the latest by November 1999.

This Amendment to the European Standard EN 552:1994 has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

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.

Amendment to EN 552

Delete clause A.4.1 in its entirety and substitute the following text.

'A.4.1. Guidance in relation to product-specific sterilizing doses (4.2.1)'

Documented procedures are available for use in establishing a *sterilizing dose*, based upon a knowledge of the number and the response to radiation of micro-organisms present in a natural state on product items. The most widely used methods are Method 1 and Method 2 described in **B.3.4.1** and **B.3.4.2**, respectively, of ISO 11137: 1995.

The appropriate Method in ISO 11137: 1995 should be followed in order to choose a *sterilizing dose* that is specific for the *medical device* of a given *primary manufacturer*.

The choice of *sterilizing dose* is made by the *primary manufacturer* of the *medical device* on the basis of experimentation to characterize the microbiological contamination on devices before sterilization and of a prediction that, at the chosen dose, the preselected SAL is achieved.

NOTE 1: The methods of *sterilization of dose* selection in ISO 11137: 1995 have been developed from computer simulation of the inactivation of micro-organisms of items undergoing irradiation treatment.

The following assumptions were made in developing the methods:

a) inactivation of any one type of micro-organism comprising the bioburden on product items can be described by a characteristic D_{10} function;

b) the probability of survival of a micro-organism is independent of the probabilities of survival of other micro-organisms present on the product item; and

c) there is a distribution of D_{10} values for the *bioburden* which is independent of *bioburden* size.

NOTE 2. Method 1 of choosing a *sterilizing dose* depends upon experimental verification that the response of the product microflora to radiation is greater than that of a microbial population having a standard distribution of resistances (or D_{10} values).

NOTE 3. The rationale for Method 2 rests on the occurrence of an approximately homogeneous microbial population (in terms of resistance or D_{10} value) on product items after exposure to a radiation dose giving a SAL of 10^{-2}. The validity of the choice of the *sterilizing dose* generally depends upon the validity of the extrapolation of the curve relating SAL and dose to doses beyond that at which SAL is 10^{-2} using an estimate of the resistance (D_{10} value) of the homogeneous population.

To choose a *sterilizing dose* using Method 1 requires substantially less resource than that required for Method 2 and, for this reason, most *primary manufacturers* prefer to make use initially of Method 1 when instituting a dose selection activity.

For product for which a specific *sterilizing dose* has been chosen, it is particularly important that the microbiological quality, defined in terms of the number of contaminating micro-organisms and their response to radiation, remains stable with time. To gain assurance of this stability and of the continued effectiveness of the *sterilizing dose* in attaining the preselected SAL, there is a requirement for the regular performance of *sterilizing dose auditing*. One approach to dose auditing is to use Method 1 or Method 2 at a stipulated frequency. An alternative approach is to use the method of dose auditing described in **B.3.5** of ISO 11137: 1995 (See note 4 below).

Practical issues to be addressed in applying Methods 1 and 2 include the following:

For Method 1

1. choice of test conditions (medium composition, temperature of incubation, etc.) for use in the estimation of product *bioburden* and in the '*verification dose*' experiment;

2. validation of microbiological test methods;

3. variation in the 'delivered dose' throughout product units exposed to the nominal '*verification dose*'.

4. frequency of performance of *sterilizing dose auditing* procedure

For Method 2

1. choice of sterility test conditions (medium composition, temperature of incubation, etc.) for use in the 'incremental dose experiment:'

2. variation in the 'delivered dose' throughout units exposed to a nominal 'incremental dose';

3. frequency of performance of *sterilizing dose auditing* procedure.

NOTE 4. In applying the *sterilizing dose auditing* method, the test conditions should be the same as those used originally in Method 1 or Method 2 when establishing the *sterilizing dose*. The dose auditing method should be used at a frequency of not less than once every three months, unless otherwise justified.

Delete A.4.2.1 in its entirety and substitute the following text.

'**A.4.2.1.** Evidence that 25 kGy achieves compliance with EN 556 may be obtained from an experiment in which either Method 1 or Method 2 (see **B.3.4.1** and **B.3.4.2**, respectively, in ISO 11137: 1995) is applied to product which is to be sterilized by exposure to this minimum dose. The calculated *sterilizing dose* derived from such an experiment should be less than 25 kGy.

Practical issues to be addressed in carrying out the experiment are:

a) when appropriate, those described under Method 1 or Method 2 above; and

b) the frequency of performance of this confirmatory experiment.

Clause A.8.2.3 In line 3, delete '(recordings?)'.

Annex B. Delete the references to 'AAMI RS-3/84, ANSI/AAMI ST 31-1990 and ANSI/AAMI ST 32-1991' in their entirety.

After the reference to 'EN 29004' insert the following:

'ISO 11137: 1995	Sterilization of health care products - Requirements for validation and routine control - Radiation sterilization'.