SLOVENSKI STANDARD
SIST EN 552:2000/A2:2001

01-november-2001

Sterilizacija medicinskih pripomoļ kov - Validacija in rutinska kontrola 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 de la stérilisation par irradiation

Ta slovenski standard je istoveten z: **EN 552:1994/A2:2000**

ICS:

11.080.01	Sterilizacija in dezinfekcija na splošno	Sterilization and disinfection in general

SIST EN 552:2000/A2:2001 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 552:1994/A2

November 2000

ICS 11.080.01

English version

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

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

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

This amendment A2 modifies the European Standard EN 552:1994; it was approved by CEN on 27 October 2000.

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 Management Centre 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 Management Centre 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/A2:2000 to the 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 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).

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 May 2001, and conflicting national standards shall be withdrawn at the latest by May 2001.

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.

Explanatory note.

This amendment to EN 552: 1994 has been prepared to resolve differences in interpretation in the technical requirements for establishing the sterilizing dose. This amendment has been prepared in accordance with Resolution 2/1998 of CEN TC 204.

The intention of this amendment is to confirm that the form of radiation to be used for routine processing has to be used in establishing the sterilizing dose.

Delete subclause 4.2.1 b) and substitute the following text.

b) Access to a source of radiation capable of precisely and accurately delivering a dose less than the *sterilizing dose* or a series of doses ranging from 1 kGy upwards. If a gamma irradiator is to be employed for routine processing, a ^{60}Co or ^{137}Cs radiation source shall be used. If an electron irradiator is to be employed for routine processing, an electron irradiator using the same operating conditions as those to be employed routinely shall be used.

The tolerances within which the delivered dose may fall can vary according to the magnitude of the target dose; the rationale for the choice of these tolerances shall be documented and their values shall be specified.