SLOVENSKI STANDARD
SIST EN 1174-1:2000

01-januar-2000

Sterilizacija medicinskih pripomoļ kov - Ocena populacije mikroorganizmov na izdelku - 1. del: Zahteve

Sterilization of medical devices - Estimation of the population of micro-organisms on product - Part 1: Requirements

Sterilisation von Medizinprodukten - Schätzung der Population von Mikroorganismen auf einem Produkt - Teil 1: Anforderungen

Stérilisation des dispositifs médicaux - Estimation de la population de micro-organismes sur un produit - Partie 1: Exigences

Ta slovenski standard je istoveten z: **EN 1174-1:1996**

ICS:

07.100.10	Medicinska mikrobiologija	Medical microbiology
11.080.01	Sterilizacija in dezinfekcija na splošno	Sterilization and disinfection in general

SIST EN 1174-1:2000 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 1174-1

February 1996

ICS 07.100.10; 11.080

Descriptors: medical equipment, sterilization, quality, estimation, contamination, designation, micro-organisms, microbiological analysis, inspection

English version

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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.

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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 204 "Sterilization of Medical Devices", the secretariat of which is held by BSI.

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of an identical text or by endorsement, at the latest by August 1996, and conflicting national standards shall be withdrawn at the latest by August 1996.

This European Standard has been prepared under a mandate given to CEN/CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directives.

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this standard.

This European Standard consists of a series of standards. It includes the following parts:

EN 1174 Sterilization of medical devices - Estimation of the population of micro-organisms -

- Part 1: Requirements
- Part 2: Guidance
- Part 3: Guide to the methods for validation of microbiological techniques

This standard has been considered by CEN/TC 204 as one of a sequence of European standards concerned with three common sterilization processes and their control. These standards are:

EN 550 Sterilization of medical devices - Validation and routine control of ethylene oxide sterilization

EN 552 Sterilization of medical devices - Validation and routine control of sterilization by irradiation

EN 554 Sterilization of medical devices - Validation and routine control of sterilization by moist heat

EN 556 Sterilization of medical devices - Requirements for medical devices to be labelled 'STERILE'

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

A sterile product item is one which is free of viable micro-organisms. The European standards for *medical devices* require, when it is necessary to supply a sterile product item, that adventitious microbiological contamination of a *medical device* from all sources is minimized by all practical means. Even so, product items produced under standard manufacturing conditions in accordance with the requirements for quality systems for medical devices (see EN 46001 or EN 46002) may, prior to sterilization, have micro-organisms on them, albeit in low numbers. Such product items are non-sterile. The purpose of sterilization processing is to inactivate the microbiological contaminants and thereby transform the non-sterile items into sterile ones.

The inactivation of a pure culture of micro-organisms by physical and/or chemical agents used to sterilize *medical devices* often approximates to an exponential relationship; inevitably this means that there is always a finite probability that a micro-organism may survive regardless of the extent of treatment applied. For a given treatment, the probability of survival is determined by the number and resistance of micro-organisms and by the environment in which the organisms exist during treatment. It follows that the sterility of any one item in a population of items subjected to sterilization processing cannot be guaranteed and the sterility of the processed population of items is defined in terms of the probability of the existence of a non-sterile item in that population.

Requirements for the quality system for the design/development, production, installation and servicing of *medical devices* are given in EN 46001 and EN 46002 which supplement the EN ISO 9000 series of European Standards. The EN ISO 9000 series of standards designates certain processes used in manufacture as 'special' if the results cannot be fully verified by subsequent inspection and testing of the product. Sterilization is an example of a special process because process efficacy cannot be verified by inspection and testing of the product. For this reason, sterilization processes need to be validated before use, the performance of each process monitored routinely and the equipment properly maintained.

European standards specifying procedures for the validation and routine control of the processes used for the sterilization of *medical devices* have been prepared (see EN 550, EN 552 and EN 554). However, it is important to be aware that exposure to a properly validated and accurately controlled sterilization process is not the only factor associated with the provision of assurance that the product is sterile and, in this respect, suitable for its intended use. Indeed for the effective *validation* and routine control of a sterilization process, it is also important to be aware of the microbiological challenge which is presented to that process, both in terms of number, identities and properties of micro-organisms.

The pre-sterilization microbiological contamination is the sum of contributions from a number of sources: therefore it is important also to give attention to factors including the microbiological status of incoming raw materials and/or components, their subsequent storage and the control of the environment in which the product is manufactured, assembled and packaged.

The term *bioburden* is commonly used to describe the population of viable micro-organisms present on a material or *product*. It is not possible to determine the exact *bioburden* and therefore, in practice, a *viable count* is determined using a defined technique. Validation exercises are performed to relate this *viable count* to a *bioburden estimate* on a material or *product* by application of a *correction factor*.

The knowledge of the *bioburden* results from the investigation of microbiological contamination levels. *Bioburden* estimations are performed in a number of separate situations as part of the:

a) *validation* and *revalidation* of a sterilization process for which the extent of exposure to sterilizing conditions is to be directly related to the *bioburden estimate*;

b) *validation* and *revalidation* of a sterilization process for which the extent of exposure to sterilizing conditions is not to be directly related to the *bioburden estimate*, but for which a general knowledge of *bioburden* is required;

c) routine control of the manufacturing process for a sterile product for which sterilization *validation* was as stated in a) above;

d) routine control of the manufacturing process for a sterile product for which sterilization *validation* was as stated in b) above.

Bioburden estimations may also be employed as part of the quality system for the manufacture of *medical devices* as an element of:

e) an overall environmental monitoring programme;

f) the assessment of the efficacy of a cleaning process in removing micro-organisms;

g) the process monitoring for products which are supplied non-sterile but for which the microbiological cleanliness is specified;

h) the monitoring of raw materials, components or packaging.

The estimation of the *bioburden* of a *medical device* generally consists of four distinct stages:

- removal of micro-organisms from the *medical device*;

- transfer of these isolated micro-organisms to *culture conditions*;

- enumeration of the micro-organisms with subsequent characteristics;

- application of the *correction factor(s)* determined during *bioburden* recovery studies in order to calculate the *bioburden estimate* from the *pre-sterilization count*.

It is not possible to define a single technique to be used for the removal of micro-organisms in all situations because of the wide variety of materials for construction and design of *medical devices*. Furthermore, the selection of conditions for enumeration will be influenced by the types of contaminant which may be anticipated.

This part of the standard therefore specifies the general criteria to be applied to the estimation of *bioburden*. Parts 2 and 3 of this European standard provide guidance on techniques which may be suitable in particular applications and methods which can be used for validating the techniques.

1 Scope

1.1 This Part of EN 1174 specifies general criteria to be applied in the estimation of the population of viable micro-organisms on a *medical device* or on a component, raw material or package. This estimation consists of both enumeration and characterization of the population.

NOTE 1: Prior to routine use, a technique for estimating the population of micro-organisms on *product* is validated. The level to which, during characterization, identification is necessary is dependent on the use to be made of the data generated.

NOTE 2: Parts 2 and 3 of this European Standard will provide guidance on selection of a technique and outline method(s) which may be used to validate the technique selected.

NOTE 3: A bibliography of useful standards is given in annex A.

1.2 This Part of EN 1174 is not applicable to the enumeration or identification of viral contamination.

1.3 This Part of EN 1174 is not applicable to the microbiological monitoring of the environment in which *medical devices* are manufactured (see Note 1).

NOTE 1: Standards on environmental monitoring are being prepared by CEN/TC 243.

NOTE 2: Attention is drawn to the standards for quality systems (see EN 46001 or EN 46002) which control all stages of manufacture including the sterilization process. It is not a requirement of this standard to have a complete quality system during manufacture but certain elements of such a system are required and these are normatively referenced at appropriate places in the text.

2 Normative references

This Part of the European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited in appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revision of any of these publications apply to this Part of 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 ISO 9001 : 1994	Quality systems - Model for quality assurance in design, development, production, installation and servicing (ISO 9001:1994)
EN 46001 : 1993	Quality systems - Medical devices - Particular requirements for the application of EN 29001