SLOVENSKI STANDARD
SIST EN 1174-2:2000

01-januar-2000

Sterilizacija medicinskih pripomoļ kov - Ocena populacije mikroorganizmov na izdelku - 2. del: Navodilo

Sterilization of medical devices - Estimation of the population of micro-organisms on product - Part 2: Guidance

Sterilisation von Medizinprodukten - Schätzung der Population von Mikroorganismen auf einem Produkt - Teil 2: Leitfaden

Stérilisation des dispositifs médicaux - Estimation de la population de micro-organismes sur un produit - Partie 2: Lignes directrices

Ta slovenski standard je istoveten z: **EN 1174-2:1996**

ICS:

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

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English version

Sterilization of medical devices - Estimation of the population of micro-organisms on product - Part 2: Guidance

Stérilisation des dispositifs médicaux - Estimation de la population de micro-organismes sur un produit - Partie 2: Lignes directrices

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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.

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, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and 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 204 "Sterilization of medical devices", the secretariat of which is held by BSI.

Annex A is informative.

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 Directive(s).

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

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 1997, and conflicting national standards shall be withdrawn at the latest by May 1997.

This standard has been considered by CEN/TC 204 as one of a sequence of European standards concerned with the estimation of the population of micro-organisms (bioburden) on product to be sterilized or after sterilization. EN 1174 has been prepared in three Parts, as follows:

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

Part 1: Requirements

Part 2: Guidance

Part 3: Guide to the methods for validation of microbiological techniques.

According to the CEN/CENELEC Internal Regulations, the national standards organizations 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

Requirements for the estimation of the population of micro-organisms on product (this population is commonly known as the bioburden) during the manufacture of medical devices are specified in EN 1174-1. This Part of EN 1174 contains guidance on the implementation of EN 1174-1. Methods other than those given in the guidance can be used but these alternative methods should be demonstrated as being effective in achieving compliance with the requirements of EN 1174-1.

1 Scope

This Part of this European Standard provides guidance on the implementation of the requirements specified in EN 1174-1. It is aimed at providing a better understanding of EN 1174-1 as well as assisting in implementing its requirements. The guidance given is not intended to be exhaustive, but to highlight important aspects to which attention should be given.

NOTE: This Part of EN 1174-1 is informative and does not contain requirements.

This Part of this European standard is not intended as a checklist for assessing compliance with EN 1174-1.

2 Normative reference

This European Standard incorporates, by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to 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 1174-1: 1996	Sterilization of medical devices - Estimation of the population of micro-organisms on product - Part 1: Requirements

3 Definitions

For the purposes of this Part of EN 1174, the definitions given in EN 1174-1 : 1996 apply.

4 General

4.1 Operation of the laboratory

In order that the data obtained from performing bioburden[1)] estimations will be reliable and reproducible, it is important that the estimations are performed under controlled conditions. The laboratory facilities used for the estimations, whether on the site of the manufacturer of the medical device or located at a remote location, should therefore be managed and operated in accordance with a documented quality system.

If bioburden estimations are performed in a laboratory under the direct management of the manufacturer of the medical device, the operation of the laboratory should be within the manufacturer's quality system. If an external laboratory is used, it is recommended that such a laboratory should be formally certified against EN 45001.

Any laboratory should be committed to providing a quality service and this commitment should be documented as a quality policy. The lines of authority and responsibility within the laboratory organization should be formally established and documented. An individual should be nominated to be responsible for the establishment of the laboratory quality system and have sufficient authority to ensure that the system is implemented.

The operation of the laboratory should be subject to regular internal audits. The results of the audit should be documented and reviewed by the laboratory management.

Further information on quality management is available in EN 29004. EN 45001 outlines requirements for a laboratory quality system and particular requirements for quality systems for medical device manufacture are specified in EN 46001 and EN 46002.

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1) See Introduction.

4.2 Equipment and materials

4.2.1 *Electronic data processing*

Computers may be used in laboratories for both direct and indirect collection, processing and/or storage of data. Both the hardware and software used for such applications should be controlled.

The computer system in use should be identified, both in terms of hardware and software, and any changes in either of these aspects should be documented and subject to appropriate approval.

For software, there should be documentation describing:

a) the applications software run on the computer system;

b) operations software;

c) data packages in use.

All software should be acceptance tested before being put into service (see, for example ISO 9000-3).

When commercial software packages are purchased, these packages should have been prepared under a quality system as described in ISO 9000-3.

When computer software is developed in-house, suitable procedures should be developed to ensure that:

1) documentation on development, including the source code, is retained;

2) records of acceptance testing are retained;

3) modifications to programs are documented;

4) changes in equipment are documented and formally tested before being put into use.

These controls should also be applied to any modification or customizing of commercial software packages.

There should be procedures to either detect or prevent unauthorized program changes.

Software programs which organize, tabulate, subject data to statistical or other mathematical procedures, or which otherwise manipulate or analyze the electronically stored data, should permit retrieval of original data entries. Special procedures for archiving computer data will probably be required and these procedures should be documented.

4.2.2 *Laboratory equipment*

There should be a system for identifying the maintenance requirements for each piece of laboratory equipment.

Equipment that does not require calibration should be clearly identified.

Any equipment, or parts thereof, that comes into contact with product, eluent, media, etc. during testing should be sterile.

4.3 Microbiological media

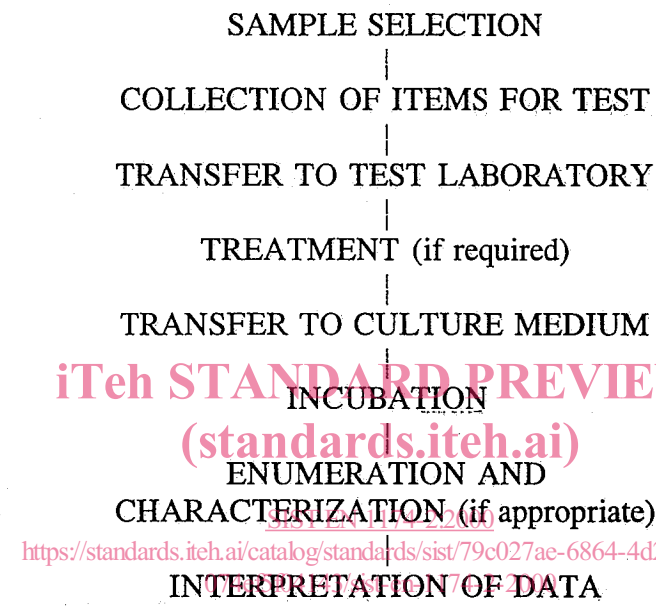
All microbiological media, and eluents used to remove micro-organisms from product, should be prepared in a manner that ensures their sterility.

The ability of microbiological medium to support growth of micro-organisms should be established. This is commonly achieved by performing a growth promotion test on each batch of medium using an inoculum of low numbers (between 10 and 100 colony-forming units) of selected micro-organisms. Growth support tests are described in Pharmacopoeial monographs and these monographs detail which micro-organisms may be suitable.

5 Selection of technique

5.1 General

The sequence of key stages of the technique for the estimation of microbial contamination is illustrated as follows:



The individual responsible for the conduct of such estimations should use knowledge of the raw materials, components, manufacturing environment, production process and the nature of the product to select appropriate methods for each of these stages.

As indicated in the introduction to EN 1174-1, bioburden estimations may be employed in a variety of situations. The responsible individual should take account of the particular situation in deciding the sampling rate, range of culture media and incubation conditions, together with the extent of method development and validation. Documenting these considerations, and the rationales for decisions taken, assists in subsequent review of procedures.

If the bioburden estimate is to be used to established directly the extent of exposure to sterilizing conditions, consideration should be given to including packaging materials within the programme for estimation of bioburden.

Ideally, bioburden should be estimated for each product on a regular basis. However, given the wide variety of products manufactured, often in small batches, this is not always practicable and, in such circumstances, products may be grouped on the basis of product type and equivalence of manufacturing environment and processes, and raw materials used. The rationale for amalgamating products into such groups should be documented and should ensure that the data are representative of all products in the group.

5.2 Elements of bioburden estimation

5.2.1 *General*

Methods of taking and handling samples should be chosen and performed to avoid the introduction of inadvertent contamination and significant alterations to the numbers and nature of micro-organisms in the sample. Sampling systems should be consistent to allow comparisons to be made over a period of time.

Generally, micro-organisms are transferred from the item being tested, or a representative portion thereof, to a culture medium by immersing, rinsing or dissolving in an eluent. The eluent may then be passed through a membrane filter which is itself placed on a culture medium or directly plated onto culture medium. Large indivisible items may be tested by methods used for surface sampling (see **5.2.4.7, 5.2.4.8** and **5.2.4.9**).

Recovery of micro-organisms from product surfaces may be enhanced by the presence of surface active agents in the eluent and by subjecting the product to a physical treatment whilst in the liquid. Commonly used eluents are discussed in **5.2.5**.

5.2.2 *Sample selection*

5.2.2.1 In choosing the sample of product for pre-sterilization counts there are two possibilities:

a) take product at random prior to sterilization;

b) take product that is not suitable for sale which may be a scrap or otherwise rejected product.

The choice for such a sample may depend on many factors but the first prerequisite is that the sample should reflect as closely as possible the product as it is presented for sterilization. If the decision is made to utilize rejected product, it should be taken so that the product has undergone all essential stages of production, including possible cleaning and packaging processes. Product selected as indicated in a) above represents the more desirable sample.

Different strategies may be employed in the selection of a sample for bioburden estimation for other purposes, such as validating cleaning or assessing production processes.

5.2.2.2 Whenever practicable, the bioburden estimation should utilize the whole product although this may not be feasible because the product cannot be accommodated in available laboratory glassware. In the latter instance, as large a portion of the product as possible should be used and the portion should allow, at completion of the estimation, the bioburden on the whole product to be estimated. Therefore, careful selection of the portion of the product to be used is important when large products like surgical gowns or external drainage kits are tested.

5.2.2.3 When sampling for estimating the bioburden, care should be taken that the products are contained in their standard packaging.

When portions of the product are taken for bioburden testing, care should be taken during manipulations of the product. If portions have to be separated from the products, this should be done under clean conditions (e.g. inside a laminar flow cabinet) in order to avoid adding contamination.

5.2.3 ***Sampling frequency***

The frequency of bioburden estimation should be established on the basis of a variety of factors including:

a) data from previous bioburden estimations;
b) the use to be made of the estimates;
c) the manufacturing processes used;
d) batch sizes;
e) production frequency for the product;
f) the materials used;
g) variations in bioburden estimates.

Sampling may be performed at a frequency based on time, e.g. monthly, or on production volume, e.g. alternate batches. However, in order to establish baseline levels, it is common practice to perform bioburden estimations at a high frequency during the initial production of a new product and for this frequency to be reduced as the knowledge of the bioburden develops (see also **7.4**).

The frequency of bioburden estimations should allow detection of changes in bioburden due to, for example, seasonal variations, manufacturing changes or changes in materials.