SLOVENSKI STANDARD
SIST EN 1174-3:2000

01-januar-2000

Sterilizacija medicinskih pripomoḷ kov - Ocena populacije mikroorganizmov na izdelku - 3. del: Vodilo za validacijske metode mikrobiloġkih postopkov

Sterilization of medical devices - Estimation of the population of micro-organisms on product - Part 3: Guide to the methods for validation of microbiological techniques

Sterilisation von Medizinprodukten - Schätzung der Population von Mikroorganismen auf einem Produkt - Teil 3: Leitfaden zu den Validierungsverfahren für mikrobiologische Methoden

Stérilisation des dispositifs médicaux - Estimation de la population de micro-organismes sur un produit - Partie 3: Lignes directrices concernant les méthodes de validation des techniques microbiologiques

Ta slovenski standard je istoveten z: EN 1174-3:1996

ICS:

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

SIST EN 1174-3:2000 en

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 1174-3

November 1996

ICS 07.100.10; 11.080

Descriptors: medical equipment, medical devices, sterilization, quality, estimation, contamination, designation, microorganisms, microbiological analysis, inspection

English version

Sterilization of medical devices - Estimation of the population of micro-organisms on product - Part 3: Guide to the methods for validation of microbiological techniques

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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
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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.

Annexes A and B are informative.

This European Standard 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).

For relationship with EU Directive(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

This Part of EN 1174 describes approaches that may be used for the validation of a technique for the estimation of bioburden. These general approaches are intended to provide guidance on the implementation of the requirements of EN 1174-1. Approaches other than those outlined here may be used.

The judgement of suitably trained and qualified personnel needs to be applied in the correct application of these approaches and, in particular, it is important to take account of product configuration and situations in which certain contaminants are sought amongst the bioburden.

1 Scope

This Part of EN 1174 gives guidance by describing approaches which may be taken when validating techniques for bioburden estimation.

This guidance is not intended to be exhaustive but is intended to highlight important aspects of methodology to which attention should be given.

This document is informative and does not contain requirements.

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

4 Validation of the technique for removal of micro-organisms from product

NOTE: This document outlines two approaches to validation of the removal of micro-organisms from product which are introduced in 6.2 of EN 1174-2:1996. In **4.1** a repetitive treatment method (see 6.2.2 of EN 1174-2:1996) is described and in **4.2** a method using inoculated product (see 6.2.3 of EN 1174-2:1996) is described.

4.1 Validation using repetitive treatment

NOTE: This approach uses the bioburden as it occurs naturally on product for the validation of the process. Sometimes it is referred to as "exhaustive recovery".

4.1.1 Before starting the process of validating a technique for removing micro-organisms from product, the technique which is to be validated should be defined and documented.

NOTE: It is important that, once a validation exercise is started, the technique is not modified. Therefore, in order to define the technique, it may be necessary to undertake preliminary experiments to identify and optimize the technique which will be validated.

4.1.2 A number of products, or parts thereof, for which the recovery efficiency is to be determined, should be selected. Each product should be individually subjected to the defined technique (see **4.1.1**) to estimate the number of micro-organisms on the product.

Having established the estimate for the product, the technique may then be applied again to the same product to establish if further micro-organisms are removed. This process of applying the technique to the same product may be repeated on a defined number of occasions.

NOTE: The exact number of repetitions which are applied will depend upon a number of factors including the nature of the product, the micro-organisms which comprise the bioburden and the initial contamination level. Preliminary experiments (see **4.1.1**) may be used to establish the number of repetitions to be applied.

4.1.3 For certain products, to establish if there are viable micro-organisms remaining on the product after repetitive treatment it is recommended to either:

a) coat the surface of the product with molten recovery medium, allowed to solidify and the product exposed to specified culture conditions (see 5.2.4.9 in EN 1174-2:1996) before the colonies formed on incubation are counted; or

b) immerse the product in liquid recovery medium, exposed to specified culture conditions and examined for growth.

NOTE : If, after immersion in liquid medium and culture, a fraction of the products indicate the presence of viable micro-organisms, the results may be utilized for enumeration by the Most Probable Number (MPN) method (see 5.2.6.7 in EN 1174-2:1996). However, if all the results show growth, the MPN method cannot be applied and the method of validation should be reconsidered.

4.1.4 The number of colonies counted after initial application of the removal technique (see **4.1.2**) is expressed as a fraction of the total number of colonies counted.

NOTE : The fraction of the total number of colonies can be calculated for each product and used to establish a removal efficiency. **A.2.1** to this Part of EN 1174 provides a worked example.

4.2 Validation using inoculated product

4.2.1 Before starting the process of validating a technique for removing micro-organisms from product, the technique which is to be validated should be defined and documented.

NOTE: It is important that, once a validation exercise is started, the technique is not modified. Therefore, in order to define the technique, it may be necessary to undertake preliminary experiments to identify and optimize the technique which will be validated.

4.2.2 A suspension of the micro-organisms with which the product is to be inoculated should be prepared and its viable count determined.

NOTE: The choice of micro-organism to be used when validating by product inoculation is discussed in 6.2.3 of EN 1174-2:1996. It is important that the micro-organisms selected for inoculation are capable of resisting drying and therefore aerobic bacterial spores are commonly used. Spores of *Bacillus subtilis* var *niger* have been found convenient because of their availability; an aqueous suspension of *Bacillus subtilis* var *niger* conforming to prEN 866-2 may be suitable.

4.2.3 An appropriate dilution of this suspension should be prepared and the viable count of this dilution determined.

NOTE: Preliminary experiments may be necessary to establish the appropriate dilution (see **4.2.1**). The viable count of the inoculum should be of the same order of magnitude as the natural contamination on a product. For items with a low bioburden, a volume of suspension of suitable concentration to deposit approximately 100 viable micro-organisms on to the product may be appropriate.

4.2.4 A number of sterile products, or parts thereof, for which the recovery efficiency is to be determined should be selected. Each product is inoculated with a volume of the suspension of micro-organisms (see **4.2.3**) and, if appropriate for the particular product, allowed to dry under laminar air flow conditions.

NOTE 1: If the item has been sterilized by ethylene oxide, it should be fully aerated to reduce the influence of any residuals. Any inhibitory effects of substances eluted from the product should be investigated in preliminary experiments (see **4.2.1** and clause **6**).

NOTE 2: The suspension should be distributed on the product in such a way that the part from which it is most difficult to remove natural contamination is included.

4.2.5 The defined technique (see **4.2.1**) is employed to establish the number of inoculated micro-organisms which are removed from the product.

4.2.6 The number of micro-organisms removed is expressed as a fraction of the number inoculated onto the product.

NOTE 1: This fraction can be calculated for each product (see **4.2.4**) and used to establish a removal efficiency. **A.2.2** to this Part of EN 1174 provides a worked example.

NOTE 2: The results derived from the validation of bioburden recovery method involving direct inoculation should be considered with caution as this method may not mimic exactly the true bioburden.