FINAL DRAFT

AMENDMENT

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Sterilization of health care products — Microbiological methods —

Part 1: Determination of a population of microorganisms on products

AMENDMENT 1

Stérilisation des produits de santé — Méthodes microbiologiques — Partie 1: Détermination d'une population de microorganismes sur des produits

AMENDEMENT 1

ISO/CEN PARALLEL PROCESSING

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Foreword

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This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

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Sterilization of health care products — Microbiological methods —

Part 1: Determination of a population of microorganisms on products

AMENDMENT 1

Clause 4

Replace with the following:

4 General

4.1 The development, validation and routine control of a sterilization process is a critical element in product realization of health care product. To ensure the consistent implementation of the requirements specified in this document, the necessary processes need to be established, implemented and maintained. Processes of particular importance in relation to the development, validation and routine control of a sterilization process include but are not limited to:

— control of documentation, including records,

— assignment of management responsibility,

— provision of adequate resources, including competent human resources and infrastructure,

— control of product provided by external parties,

— identification and traceability of product throughout the process, and

— control of non-conforming product.

NOTE ISO 13485 covers all stages of the lifecycle of medical devices in the context of quality management systems for regulatory purposes. National and/or regional regulatory requirements for the provision of health care product can require the implementation of a full quality management system and the assessment of that system by a recognized conformity assessment body.

4.2 A process shall be specified for the calibration of all equipment, including instrumentation for test purposes, used in meeting the requirements of this document.

B.3.3.4

B.3.3.4 MPN methods are simple to perform, and the statistical basis for the method makes it more appropriate for general assessment rather than accurate determinations. The MPN method for 10 samples of a single dilution is shown in Table 5 of the FDA BAM[27]. This single dilution method does not incorporate additional dilutions that could provide further information about the number of microorganisms producing a positive sample. Alternatively, Formula (B.1) can be used for individual

samples or SIPs to determine a most probable number. Formula (B.1) is a simplified version of the original formula from Cochran[42].

$$MPN\,(sd \text{ or } SIP) = \ln\left(\frac{n}{s}\right)\frac{1}{SIP} \tag{B.1}$$

where

sd is for single dilution;

ln represents natural log;

n is the total number of samples tested;

s is the number of samples negative for growth.

Bibliography

Add the following:

Cochran W. Estimation of Bacterial Densities by Means of the Most Probable Number, *Biometrics*. 6:105-116, 1950

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on active implantable medical devices [OJ L 189] aimed to be covered

This European standard has been prepared under a Commission's standardisation request M/023 to provide one voluntary means of conforming to essential requirements of Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices [OJ L 189].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with 90/385/EEC, as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with essential requirements 1, 4, 5, 8, 9 and 10of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 90/385/EEC [OJ L 189]

Essential Requirements (ERs) of Directive 90/385/EEC	Clauses of this EN	Qualifying remarks/Notes
7	4, 5, 6, 7, 8, 9	This standard addresses the determination of the population of micro-organisms on or in a medical device as part of the validation and routine control of a sterilization process. This relevant Essential Requirement is partly addressed in this European Standard and only in conjunction with the applicable standard for validation and routine control of the sterilization process being employed. Design and packaging for maintenance of sterility during transportation and storage are not covered. Aspects of manufacture other than those related to sterilization are not covered.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.

Annex ZB
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices [OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's standardization request M/023 to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZB.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with 93/42/EEC, as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZB is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZB.1, it means that it is not addressed by this European Standard.