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AMENDMENT 1
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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

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

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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

Replace with the following:

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