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Sterilization of medical devices — Microbiological methods —

Part 3: Guidance on evaluation and interpretation of bioburden data

Stérilisation des dispositifs médicaux — Méthodes microbiologiques —

Partie 3: Lignes directrices sur l'évaluation et l'interprétation de données de charge biologique

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 11737-3 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

ISO 11737 consists of the following parts, under the general title *Sterilization of medical devices — Microbiological methods*:

— *Part 1: Estimation of population of microorganisms on products*

— *Part 2: Tests of sterility performed in the validation of a sterilization process*

— *Part 3: Guidance on evaluation and interpretation of bioburden data*

Introduction

International standards for the validation and routine control of sterilization processes have been published (ISO 11134, ISO 11135, ISO 11137, ISO 14160 and ISO 14937). These standards specify that the bioburden, i.e. the population of microorganisms present on product, be estimated during validation and that the routine control of the sterilization process include a programme of bioburden monitoring. These requirements are specified because it is important that the microbiological quality of product presented for sterilization is consistent over time, and that the level of microbiological contamination is as low as practicable taking into account the nature of the raw materials, the product itself and the processes involved in manufacture. ISO 11737-1 specifies requirements for the estimation of bioburden.

The natural microbial population on and/or in product items is the challenge to the sterilization process. Bioburden estimations, performed as part of validation, provide information about this challenge. The results of performing bioburden estimations may be used in the determination of the extent of treatment to be applied in the sterilization process (see, for example, ISO 11137). However, such application of bioburden data is particular to the method of sterilization and, therefore, is not considered in this part of ISO 11737.

The estimations performed as part of routine control are intended to detect changes in bioburden in terms of the number of contaminating microorganisms and/or the types of microorganisms present. Bioburden data are an element of the system of monitoring the effectiveness of controls applied to manufacturing processes and to the environment in which medical devices are manufactured; as such, bioburden data are part of the quality records within the quality management system (see ISO 13485). In the context of a quality management system, bioburden estimations may be an element of one or more of the following:

— an overall environmental monitoring system;

— an assessment of the effectiveness of a cleaning process in removing microorganisms;

— a programme for monitoring a manufacturing process for product supplied non-sterile but for which a level of microbiological cleanliness is specified;

— a programme of monitoring the microbiological quality of raw materials, components or packaging.

This part of ISO 11737 is intended to provide guidance only on the evaluation and interpretation of bioburden data in routine control and monitoring. The guidance given here is additional to that provided in ISO 11737-1:1995, Annex A.