INTERNATIONAL STANDARD

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Sterilization of health care products — Requirements for validation and routine control — Industrial moist heat sterilization

Stérilisation des produits sanitaires — Prescriptions pour la validation et le contrôle de routine — Stérilisation industrielle par chaleur humide

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International Organization for Standardization
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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.

International Standard ISO 11134 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

Annexes A, B and C of this International Standard are for information only.

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Introduction

The manufacture of a safe and sterile health care product requires attention to product characteristics and to sterilization methods and controls. This International Standard provides the essential elements of good manufacturing practice for moist heat sterilization of health care products.

A sterile product is one that is free of viable microorganisms. Even items produced under controlled manufacturing conditions may, prior to sterilization, have microorganisms on them. Such products are, by definition, non-sterile. The purpose of sterilization processing is to destroy the microbiological contaminants on these non-sterile products.

The destruction of microorganisms by physical and chemical agents follows an exponential law. Accordingly, one can calculate a finite probability of a surviving microorganism regardless of the magnitude of the delivered sterilization dose or treatment.

The probability of survival is a function of the number and types (species) of microorganisms present on the product, the sterilization process lethality, and, in some instances, the environment in which the organisms exist during treatment.

It follows that the sterility of individual items in a population of products sterilized cannot be guaranteed in the absolute sense. The probability of non-sterility of each individual product unit is derived mathematically. For example, with a probability of 10^{-6}, the likelihood of a non-sterile product unit is less than or equal to one in a million.

Requirements for the quality system for the design, development, production, supply, installation and servicing of health care products are given in the ISO 9000 series of Standards.

The ISO 9000 series of Standards designates certain processes used in the manufacture of health care products as "special" in that the result cannot be fully verified by subsequent inspection or testing of the product. Sterilization is an example of a special process because efficacy cannot be verified by inspection or testing of the product. For this reason, sterilization processes must be validated before use, the process routinely monitored and the equipment maintained.

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