

# norm

# NEN-EN-ISO 11135

Sterilization of health care products -  
Ethylene oxide - Requirements for  
development, validation and routine  
control of a sterilization process for  
medical devices (ISO/DIS  
11135:2004, IDT)

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May 2004

ICS

Will supersede EN 550:1994

English version

**Sterilization of health care products - Ethylene oxide -  
Requirements for development, validation and routine control of  
a sterilization process for medical devices (ISO/DIS  
11135:2004)**

Stérilisation des produits de santé - Oxyde d'éthylène -  
Exigences de développement, validation et contrôle de  
routine d'un processus de stérilisation pour des dispositifs  
médicaux (ISO/DIS 11135:2004)

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 204.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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## Foreword

This document (prEN ISO 11135:2004) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with Technical Committee CEN/TC 204 "Sterilization of medical devices", the secretariat of which is held by BSI.

This document is currently submitted to the parallel Enquiry.

This document will supersede EN 550:1994.

This document 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 document.

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**ANNEX ZA**  
(informative)

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## Sterilization of health care products — Ethylene oxide — Requirements for development, validation and routine control of a sterilization process for medical devices

*Stérilisation des produits de santé — Oxyde d'éthylène — Exigences de développement, validation et contrôle de routine d'un processus de stérilisation pour des dispositifs médicaux*

[Revision of first edition (ISO 11135:1994)]

ICS 11.080.01

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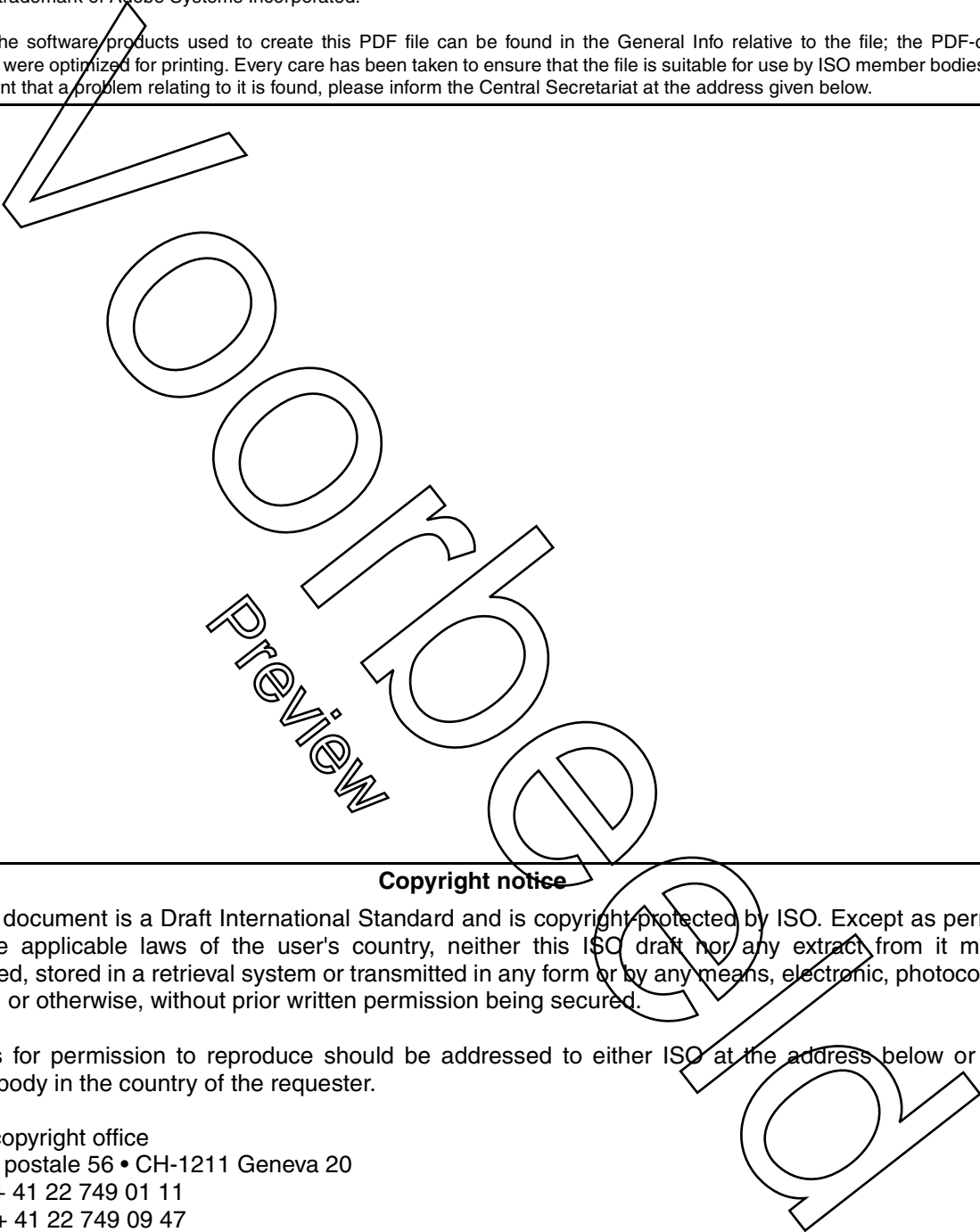
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ISO 11135 was prepared by Technical Committee ISO/TC 198.

This second edition cancels and replaces the first edition and has been extensively revised.

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## Introduction

A sterile medical device is one which is free of viable microorganisms. International Standards, which specify requirements for validation and routine control of sterilization processes, require, when it is necessary to supply a sterile medical device, that adventitious microbiological contamination of a medical device prior to sterilization be minimised. Even so, medical devices produced under standard manufacturing conditions in accordance with the requirements for quality management systems (see, for example, ISO 13485) may, prior to sterilization, have microorganisms on them, albeit in low numbers. Such products are non-sterile. The purpose of sterilization is to inactivate the microbiological contaminants and thereby transform the non-sterile products into sterile ones.

The kinetics of inactivation of a pure culture of microorganisms by physical and/or chemical agents used to sterilize medical devices can generally best be described by an exponential relationship between the numbers of microorganisms surviving and the extent of treatment with the sterilizing agent; inevitably this means that there is always a finite probability that a microorganism may survive regardless of the extent of treatment applied. For a given treatment, the probability of survival is determined by the number and resistance of microorganisms and by the environment in which the organisms exist during treatment. It follows that the sterility of any one product in a population subjected to sterilization processing cannot be guaranteed and the sterility of a processed population is defined in terms of the probability of there being a viable microorganism present on a product.

This International Standard describes requirements which will enable the demonstration that an ethylene oxide sterilization process intended to sterilize medical devices has appropriate microbicidal activity. This activity is both reliable and reproducible, such that the relationship for the inactivation of microorganisms can be extrapolated with reasonable confidence to low levels of probability of there being a viable microorganism present on a product after sterilization processing. This international standard does not specify the maximal value to be taken by this probability; specification of this probability is a matter for regulatory authorities and may vary from country to country (see, for example, EN 556-1 and ANSI/AAMI ST67).

Generic requirements of the quality management systems for design/development, production, installation and servicing are given in ISO 9001 and particular requirements for quality management systems for medical device production in ISO 13485. The standards for quality management systems recognise that, for certain processes used in manufacturing or reprocessing, the effectiveness of the process cannot be fully verified by subsequent inspection and testing of the product. Sterilization is an example of such a process. For this reason, sterilization processes are validated for use, the performance of the sterilization process monitored routinely and the equipment maintained.

Exposure to a properly validated, accurately controlled sterilization process is not the only factor associated with the provision of reliable assurance that the product is sterile and, in this regard, suitable for its intended use. Attention is therefore given to a number of factors including:

- a) the microbiological status of incoming raw materials and/or components,
- b) the validation and routine control of any cleaning and disinfection procedures used on the product,
- c) the control of the environment in which the product is manufactured, assembled and packaged,
- d) the control of equipment and processes,
- e) the control of personnel and their hygiene,
- f) the manner and materials in which the product is packaged, and,
- g) the conditions under which product is stored.

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