TECHNICAL SPECIFICATION

ISO/TS 21387

First edition
2020-09

Sterilization of medical devices — Guidance on the requirements for the validation and routine processing of ethylene oxide sterilization processes using parametric release

Stérilisation des dispositifs médicaux — Lignes directrices concernant les exigences de validation et de traitement de routine des procédés de stérilisation à l'oxyde d'éthylène par libération paramétrique

Reference number
ISO/TS 21387:2020(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

ISO 11135 includes requirements for development, validation and routine control of ethylene oxide (EO) sterilization processes. This document is intended to be used in conjunction with ISO 11135.

ISO 11135:2014:11.1 refers to criteria for designating conformity of the sterilization process used for a particular sterilization load as including:

a) confirmation that the data recorded during routine processing meet the sterilization process specification;

b) confirmation of no growth of the test organism for any biological indicator (BI) (if used).

Parametric release is the declaration of adequacy of routine processing for a validated sterilization process based solely on measurement and documentation of physical process parameters rather than results of BIs, therefore b) does not apply.

The term BI release is used when the declaration of adequacy of the validated sterilization cycle includes a requirement for no growth in BIs exposed to that cycle.

The guidance in this document is informative and is not intended as a checklist for auditors. The guidance in this document provides examples of methods considered to be suitable as a means for conforming with the requirements of ISO 11135.

NOTE Sterilization in health care facilities differs from industrial sterilization, for example, the design of processing areas, control of product bioburden, access to relevant expertise in EO sterilization and sterilization equipment that might not be equipped to enable consideration of parametric release.

This guidance is intended for people who have knowledge of the principles of EO sterilization. Methods other than those given in the guidance can be used if they are effective in achieving conformity with the requirements of ISO 11135.