
**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*



This document is a preview generated by EUS



COPYRIGHT PROTECTED DOCUMENT

© ISO 2020

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Quality management systems	2
5 Sterilization agent characterization	2
6 Process and equipment characterization	2
6.1 General	2
6.2 Process characterization	2
6.3 Equipment characterization	2
7 Product definition	4
7.1 General	4
7.2 Product safety, quality and performance	4
7.3 Microbiological quality	4
8 Process definition	5
9 Validation	5
9.1 General	5
9.2 Installation qualification	6
9.2.1 Equipment	6
9.2.2 Installation qualification	7
9.3 Operational qualification	7
9.4 Performance qualification	8
9.4.1 General	8
9.4.2 Performance qualification — Microbiological	9
9.4.3 Performance qualification — Physical	9
9.5 Review and approval of validation	9
10 Routine monitoring and control	10
11 Product release from sterilization	11
12 Maintaining process effectiveness	12
12.1 General	12
12.2 Maintenance of equipment	12
12.3 Requalification	12
12.4 Assessment of change	12
12.5 Assessment of equivalence	13
13 ISO 11135:2014, Annex A	13
14 ISO 11135:2014, Annex B	13
Annex A (informative) Establishing specifications for parametric release based on routine processing data	14
Bibliography	17

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.

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

1 Scope

This document provides guidance on the requirements of ISO 11135 that apply when parametric release is used to release the product after exposure to the sterilization process. It provides a path for transition of existing cycles, as well as a path for the development and implementation of a parametric release specification for a new cycle. Additionally, it highlights the importance and interrelationship of other process factors, i.e. load configuration and equipment performance, which influence reproducibility of an ethylene oxide (EO) sterilization process.

NOTE For ease of reference, the numbering of clauses in this document corresponds to that in the normative parts of ISO 11135.

No additional guidance is offered for processes where the declaration of adequacy of the validated sterilization cycle includes a requirement for no growth in biological indicators (BIs) exposed to that process.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11135:2014, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11135:2014 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

absolute humidity

AH

measure of water vapour in the air, regardless of temperature

Note 1 to entry: It is expressed as grams of moisture per cubic metre of air (g/m³).

[SOURCE: ISO 11139:2018, 3.136.1]