

# Change summary for 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

Approved 5 June 2016 by  
**Association for the Advancement of Medical Instrumentation**

**Abstract:** Provides summary of differences between the new 2014 version and the 2007 version of ISO 11135. Provides end users with a quick reference when evaluating and implementing the 2014 version of ISO 11135 in their facilities.

**Keywords:** bioburden, endotoxin, guidance, load, parameter, product, qualification, requirement, specification

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**Contents**

Page

Committee representation .....iv

Introduction .....vi

Change summary..... 1

## Committee representation

### Association for the Advancement of Medical Instrumentation

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This Technical Information Report was developed by the AAMI Industrial Ethylene Oxide Sterilization Working Group. Committee approval of the TIR does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the **AAMI Industrial Ethylene Oxide Sterilization Working Group** had the following members:

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## Introduction: Need for this AAMI TIR

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* has now replaced the previous version of this standard, ISO 11135-1:2007, and its accompanying guidance document, ISO 11135-2:2008.

The purpose of this document is to provide a summary of differences between the new 2014 version and the 2007 version of this standard. The intent is to provide end users with a quick reference when evaluating and implementing the 2014 version of ISO 11135 in their facilities. The document has been created and reviewed by AAMI Working Group 1, Industrial Ethylene Oxide Sterilization. However, it should be noted that this document is a guidance or summary only, and should not be considered a complete and definitive record of all changes. Final assessment of the changes, and possible impacts of these changes, is the responsibility of the end user.

The first column of the table references the clause in ISO 11135:2014, the second column provides a description of the change from the 2007 version to the 2014 version, and the 3<sup>rd</sup> column provides an opinion on the possible impact of the change.