

# Technical Information Report

## AAMI TIR28: 2016

Product adoption and  
process equivalence for  
ethylene oxide sterilization



# Product adoption and process equivalence for ethylene oxide sterilization

Approved 18 November 2016 by  
**AAMI**

**Abstract:** This technical information report provides guidance for the adoption of new or modified products into an existing validated sterilization process and for the determination of equivalence of a sterilization process as conducted with different equipment. Guidance is intended to augment the ANSI/AAMI/ISO 11135 series in the areas of product adoption and process equivalence.

**Keywords:** sterilization, ethylene oxide, product adoption, process equivalence, product family

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

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