

Technical Information Report

ANSI/AAMI/ ISO TIR13004: 2013/(R)2016

Sterilization of health care
products—Radiation—
Substantiation of a selected
sterilization dose: Method
 VD_{max}^{SD}

Sterilization of health care products—Radiation— Substantiation of a selected sterilization dose: Method VD_{max}^{SD}

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Abstract: This Technical Specification describes a method for substantiating a selected sterilization dose of 17.5, 20, 22.5, 27.5, 30, 32.5 or 35 kGy that achieves a sterility assurance level (SAL) of 10^{-6} or less for radiation sterilization of health care products. This Technical Specification also specifies a method of sterilization dose audit used to demonstrate the continued effectiveness of the substantiated sterilization dose.

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Glossary of equivalent standards

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www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation

Radiation Sterilization Working Group

The adoption of ISO Technical Specification (TS) 13004, as an AAMI Technical Information Report was initiated by the AAMI Radiation Sterilization Working Group, which also functions as the U.S. Technical Advisory Group to the relevant work in the International Organization for Standardization (ISO). U.S. representatives from the AAMI Radiation Sterilization Working Group (U.S. Sub-TAG for ISO/TC 198/WG 2, Radiation Sterilization) played an active role in developing the ISO Technical Specification.

At the time this document was published, the **AAMI Sterilization Standards Committee** had the following members:

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