Technical Information Report

AAMI TIR76: 2021

Sterilization of health care products—Radiation—Substantiation of a selected sterilization dose at a specified sterility assurance level: Method VD_{max}^{SD-S}

AAMI
Advancing Safety in Health Technology

Sterilization of health care products—Radiation—Substantiation of a selected sterilization dose at a specified sterility assurance level: Method VD_{max}^{SD-S}

Approved 31 March 2021 by
AAMI

Abstract: This technical information report describes a method for substantiating a selected sterilization dose that achieves maximally a selected sterility assurance level (SAL) for radiation sterilization of healthcare products and a method of sterilization dose audit used to demonstrate the continued effectiveness of the substantiated sterilization dose.

Keywords: radiation sterilization, sterilization, dose, sterility assurance level, SAL, Method VD_{max}^{SD-S}

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 901 N. Glebe Road, Suite 300, Arlington, VA 22203-1633.

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Committee representation

Association for the Advancement of Medical Instrumentation

Radiation Sterilization Working Group

This technical information report was developed by the AAMI Radiation Sterilization Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the technical information report does not necessarily mean that all working group members voted for its approval.

At the time this technical information report was published, the **AAMI Radiation Sterilization Working Group** had the following members:

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