

Technical Information Report

AAMI/ISO TIR22456: 2022

Sterilization of health care products—Microbiological methods—Guidance on conducting bioburden determinations and tests of sterility for biologics and tissue-based products

Sterilization of health care products—Microbiological methods—Guidance on conducting bioburden determinations and tests of sterility for biologics and tissue-based products

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Abstract: Provides guidance for bioburden testing and tests of sterility for biologics and tissue-based products, where this testing is in relation to product sterilization.

Keywords: bioburden testing, tests of sterility, biologics, tissue-based products, sterilization

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Committee representation

Association for the Advancement of Medical Instrumentation

Microbiological Methods Working Group

The adoption of ISO/TS 22456:2021 as an AAMI Technical Information Report was initiated by the AAMI Microbiological Methods Working Group. AAMI ST-WG08 provides input to the AAMI Sterilization Standards Committee which is the responsible group for providing the U.S. input to the relevant group in the International Organization for Standardization (ISO). U.S. representatives from AAMI Microbiological Methods Working Group and the TAG played an active part in developing the ISO document.

At the time this document was published, the **AAMI Microbiological Methods Working Group** had the following members:

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