



Certification of Sterilization Validation
ISO 11137 Process Qualification (E-Beam)
Effective Date: September 2, 2025

Statement of Compliance

Scientific Specialties Inc. hereby attests that the electron-beam (e-beam) sterilization process used for the following product families has been successfully validated and is maintained in compliance with ISO 11137 - Sterilization of Health Care Products - Radiation.

Cryogenic Tube & Cap Assemblies
Screw Cap & Tube Assemblies
Microcentrifuge Tubes with Snap Caps

Sterilization Supplier:	STERIS AST (Mentor, Ohio, USA)
Sterilization Modality:	Electron-Beam (E-Beam) Irradiation
Validation Method:	VDmax17.5 Method per ISO 11137-2
Sterility Assurance Level (SAL):	$\leq 10^{-6}$
Validation Reference:	STERIS Report No. 24-097TT Sterilization Validation Report

Certification Statement

The referenced validation study demonstrates that the e-beam sterilization process achieves the specified Sterility Assurance Level ($SAL \leq 10^{-6}$) and meets all acceptance criteria defined by ISO 11137-1 and ISO 11137-2.

Scientific Specialties Inc. maintains this validated process through:

- Routine dose audits and verification per ISO 11137-1 §12
- Bioburden monitoring and trending
- Supplier qualification and periodic review of STERIS AST
- Documented process control within the Quality Management System

This declaration constitutes self-certification of conformity to ISO 11137.

ISO 11137 is a process validation standard, not a certifiable management standard; therefore, no external certification body issues certificates for ISO 11137. Compliance is demonstrated through validation, ongoing monitoring, and controlled documentation.

Sincerely,

Steven Hernandez
Customer Support/Quality Manager