The Sterile Start® Program

Tiered validation support for medical device packaging validation

Without the support of competent vendors, medical device packaging can quickly become overwhelming. At Van der Stähl Scientific, we understand that we do not simply sell medical pouch sealers. We provide complete, closed end medical device packaging solutions that help manufacturers maintain sterility from the cleanroom all the way to the patient.

Through our Sterile Start® Program, we streamline ISO 11607 readiness by giving our customers access to a full dashboard of support tools, validation resources, and engineering services. There is no need to navigate medical device packaging validation on your own when our team is prepared to support you with a wide range of ready-made solutions as well as fully customized assistance.

Our three-tier support structure is designed to meet medical device manufacturers exactly where they are in their packaging validation journey, from basic equipment readiness to full process qualification. Each tier builds on the previous one and adds deeper testing, documentation, and hands on engineering support to help you achieve ISO aligned, audit ready sterile packaging performance.

We are committed to making the validation journey clearer, faster, and more achievable for every medical device manufacturer we serve.

Tier 1 Support: Baseline Equipment Readiness

Tier 1 is provided at no cost and establishes foundational confidence that your equipment is functioning as intended upon arrival. This tier is ideal for customers beginning preliminary product testing or integrating a new machine into their cleanroom.

Purpose of Tier 1

Tier 1 ensures that your equipment is operational, stable, and ready for early-stage testing. Each checklist is tailored to the specific model purchased and verifies that the machine's core functions are performing correctly.

What Tier 1 Machine Support Includes

- Multi zone firmware driven thermal calibration. Each sealer receives a multi zone thermal calibration using proprietary firmware algorithms. Temperature accuracy is verified across backend thermal zones and certified by our ISO IEC 17025 accredited calibration laboratory.
- 35-point machine function verification. Our structured 35-point evaluation confirms proper operation of heating systems, conveyance, pressure delivery, and user interface functions.
- ASTM F88 tensile seal strength test (single pouch evaluation). A single event tensile test verifies that the machine can produce a seal that meets sterile barrier performance expectations.
- Equipment Readiness Checklist. A quick checklist your team can execute to ensure that the equipment is installed and running as intended.

Tier 1 provides a reliable baseline and gives you confidence that your equipment is ready for initial product trials and early development work.

Tier 2 Support: Formal IQ/OQ Documentation Package

Tier 2 provides a structured documentation suite that enables customers to execute Installation Qualification (IQ) and Operational Qualification (OQ) using Van der Stähl Scientific's validated protocols. This tier is ideal for organizations preparing equipment for production use while full process validation is still in development.

Purpose of Tier 2

Tier 2 accelerates your qualification timeline by providing ready to use protocols or protocol components that can be integrated into your internal templates. This allows you to generate defensible IQ/OQ reports and begin production in a controlled and compliant state.

What Tier 2 Machine Support Includes

- Multi zone firmware driven thermal calibration with ISO IEC 17025 accredited certification.
- 35-point machine function verification.
- ASTM F88 tensile seal strength testing (twenty pouch study). A 20 specimen tensile test provides statistically meaningful confirmation of seal consistency.
- ISO 17025 accredited force calibration using an external transducer and precision Futek meter.
- Equipment Validation (IQ/OQ) Protocol that your team can execute to generate an IQ/OQ Equipment Report for your QMS.

Tier 2 gives manufacturers a turnkey pathway to IQ/OQ completion, reducing internal workload and accelerating readiness for controlled production.

Tier 3 Support: Full Process Qualification (PQ) and DOE Development

Tier 3 is the most comprehensive level of support. It provides hands on engineering assistance, customized documentation, and full process qualification tailored to your specific device, materials, and packaging workflow.

Purpose of Tier 3

Tier 3 is designed for manufacturers who require complete validation support, including DOE development, OQ/PQ execution, and final reporting suitable for inclusion in the Quality Management System. This tier ensures that your sealing process is optimized, validated, and defensible during audits.

What Tier 3 Machine Support Includes

- Equipment Validation (IQ/OQ) identical to the Tier 2 package.
- Multi zone firmware driven thermal calibration with ISO IEC 17025 accreditation.
- 35-point machine function verification.
- ASTM F88 tensile seal strength testing (fifty pouch study) for robust statistical confidence.
- ISO 17025 accredited force calibration using an external transducer and Futek meter.
- Microprocessor timing verification for consistent dwell and conveyance speed.
- Custom preliminary DOE to determine how equipment factors such as seal temperature, release temperature, and dwell time affect pouch performance.
- Custom secondary DOE to determine optimal values for OQ High, OQ Low, and PQ.
- DOE Report including photos, statistical analysis, Main Effects Plot, and Interactions Plot.
- OQ/PQ protocol creation based on DOE results and risk assessment requirements.
- OQ/PQ execution and reporting performed by our engineering team.
- Customizable support levels that can scale from collaborative assistance to fully outsourced validation execution.

Tier 3 provides a complete end to end validation solution that ensures your sealing process is optimized, documented, and compliant with ISO 11607 and FDA expectations.

Meet the Experts Powering Sterile Start®

Jeff Devich, BSME, MBA

Jeff's background includes serving as Director of Operations for a combination of device contract manufacturers. He has extensive experience in equipment and process validation within the MedTech industry. Jeff applies his mathematic and engineering expertise to create Design of Experiments and characterization reports for Van der Stähl Scientific sealers, helping customers understand how process parameters affect their specific products.

Charlie Webb BS, CPPL

Charlie is a recognized leader in medical device packaging with more than 30 years of industry experience. A multi patented innovator, MDPTC instructor, Six Sigma MBB, ISO 17025 certified auditor, and respected industry speaker, he has shape best practices in sterile packaging science. Charlie also hosts the SPOT Radio medical packaging podcast, where he shares insights from years of regulatory engagement and real-world problem solving.

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Connecting medical device packaging to patient safety.

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