



CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

PRO-TECH Design & Manufacturing, Inc.

**14561 Marquardt Ave.
Santa Fe Springs, CA 90670**

Fulfills the requirements of

ISO/IEC 17025:2017

In the field of

TESTING

This certificate is valid only when accompanied by a current scope of accreditation document.
The current scope of accreditation can be verified at www.anab.org.

A handwritten signature in black ink, appearing to read 'R. Douglas Leonard Jr.', is positioned above a horizontal line.

R. Douglas Leonard Jr., VP, PILR SBU

Expiry Date: 22 December 2024

Certificate Number: AT-2938



This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017.
This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory
quality management system (refer to joint ISO-ILAC-IAF Communiqué dated April 2017).

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

PRO-TECH Design & Manufacturing, Inc.

14561 Marquardt Ave.
 Santa Fe Springs, CA 90670
 Clarissa Muraoka clarissa@protechdesign.com
 562 207 1680 ext. 214

TESTING

Valid to: **December 22, 2024**

Certificate Number: **AT-2938**

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Total Organic Carbon (TOC)	USP <643>	Medical Devices	TOC Analyzer
pH	USP <791>	Medical Devices	pH Meter
Osmolarity and Osmolality	USP <785>	Medical Devices	Osmometer
Ultraviolet / Visible Spectroscopy	USP <857>	Medical Devices	UV- Vis Spectrophotometer
Viscosity - Rotational Methods	USP <912>	Medical Devices	Rotational Viscometer

Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Bioburden	ISO 11737-1, USP <61>, USP <62>	Medical Devices	ISO Class 5 Hoods, Incubators
Limulus Amebocyte Lysate (LAL) Kinetic Chromogenic Method	USP <85>	Medical Devices	Spectrophotometer, Incubators

Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Visual Inspection	ASTM F1886	Medical Device Pouches / Trays	Lab Technician
Bubble Leak Test	ASTM F2096	Medical Device Pouches / Trays	Leak Integrity Package Tester
Peel Strength Test	ASTM F88	Medical Device Pouches / Trays	Seal Strength Tester

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-2938.



R. Douglas Leonard Jr., VP, PILR SBU

