SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

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MECHANICAL

Valid To: May 31, 2027 Certificate Number: 3561.02

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following tests on shipping containers, medical pouches, medical trays, and medical devices:

Testing is completed for the following parameters in the calibrated ranges specified below:

Parameter[1]	**Range (Units)**
Load:	0 to ±30 (kN)
Displacement:	0 to ±35 (in)
Speed:	±0.04 to ±40 (in/min)
Torque:	0 to ±5 (N·m)
Rotary displacement:	0 to 360 (°)
Rotary Speed:	0.1 to 60 (rpm)

Test:	**Test Method:**
Small-bore Connectors for Liquids and Gases in Healthcare Applications – Common Test Methods Leakage by Pressure Decay Falling Drop Positive-Pressure Liquid Leakage Subatmospheric-Pressure Air Leakage Stress Cracking Resistance to Separation from Axial Loading Resistance to Separation from Unscrewing Resistance to Overriding	ISO 80369-20
Prefilled Syringes – Glass and Plastic Barrels for Injectables and Sterilized Subassembled Syringes Ready for Filling Closure System Liquid Leakage Dye Solution Tightness Glide Force Luer Lock Adapter Collar Torque Luer Lock Rigid Tip Cap Unscrewing Torque	ISO 11040-4, ISO 11040-6

Test:	**Test Method:**
Prefilled Syringes – Glass and Plastic Barrels for Injectables and Sterilized Subassembled Syringes Ready for Filling & Finished Prefilled Syringes Luer Lock Adaptor Collar Pull-Off Force Needle Pull-Out Force Flange Breakage Resistance Luer Cone Breakage Dead Space and Residual Volume Needle Penetration	ISO 11040-4, ISO 11040-6, ISO 11040-8
Prefilled Syringes – Requirements and Test Methods for Finished Prefilled Syringes Deliverable Volume Break Loose Extrusion Force (BLEF) Dose Accuracy Burst Resistance Markings Liquid Leakage Beyond the Plunger	ISO 11040-8
Needle –Base Injection Systems for Medical Use Requirements and Test Methods Part 1: Needle Based Injection Systems Environmental Conditioning Free Fall Testing Vibration Testing Dose Accuracy	ISO 11608-1
Intravascular Catheters – Sterile and Single-use Catheters – Part 1: General Requirements Corrosion Resistance Peak Tensile Force Freedom from Leakage- Air Leakage Freedom from Leakage- Liquid Leakage Flowrate Power Injection- Burst Power Injection- Flowrate	ISO 10555-1
Sterile Hypodermic Needles for Single Use – Requirements and Test Methods Needle Penetration Tolerance on Length Needle Bonding Strength Patency of Lumen	ISO 7864

Test:	Test Method:
Sterile Hypodermic Syringes for Single Use – Syringes for Manual Use Graduated Capacity and Dead Space Graduated Scale Barrel Plunger Stopper/ Plunger Assembly Nozzle Performance	ISO 7886-1
Sterile Single Use Intravascular Introducers, Dilators, and Guidewires Flexing Test Fracture Test Peak Tensile Force Guidewires Corrosion Resistance Freedom from Leakage from Sheath Introducer Freedom form Leakage through Haemostatis Valve Strength of Union of Needle Tube and Needle Hub	ISO 11070
Infusion Equipment for Medical Use – Part 4: Infusion Sets for Single Use, Gravity Feed Positive Pressure Air Leakage Vacuum Air Leakage Closure Piercing Device Air Inlet Device Drip Chamber and Drip Tube Injection Site Flow Rate of Infusion Set Tensile Strength	ISO 8536-4
Infusion Equipment for Medical Use – Part 8: Infusion Sets for Single Use with Pressure Infusion Equipment Positive Pressure Air Leakage Positive Pressure Liquid Leakage Vacuum Air Leakage Tensile Strength Closure Piercing Device Air Inlet Device Drip Chamber and Drip Tube Injection Site Storage Volume Flow Rate of Infusion Set	ISO 8536-8

Test:	Test Method:
Infusion Equipment for Medical Use – Part 9: Fluid Lines for Single Use with Pressure Infusion Equipment Positive Pressure Air Leakage Positive Pressure Liquid Leakage Tensile Strength Storage Volume	ISO 8536-9
Infusion Equipment for Medical Use – Part 10: Accessories for Fluid Lines for Single Use with Pressure Infusion Equipment Positive Pressure Air Leakage Positive Pressure Liquid Leakage Tensile Strength Injection Site	ISO 8536-10
Infusion Equipment for Medical Use – Part 11: Infusion Filters for Single Use with Pressure Infusion Equipment Positive Pressure Air Leakage Positive Pressure Liquid Leakage Tensile Strength	ISO 8536-11
Infusion Equipment for Medical Use – Part 12: Check Valves for Single Use Positive Pressure Air Leakage Positive Pressure Liquid Leakage Vacuum Air Leakage Blocking Performance Opening Pressure Flow Rate of Infusion Set	ISO 8536-12
Infusion Equipment for Medical Use – Part 13: Graduated Flow Regulators for Single Use with Fluid Contact Positive Pressure Air Leakage Vacuum Air Leakage Tensile Strength Flow Rate with Flow Regulatory – Accuracy Flow Rate with Flow Regulatory – Stability	ISO 8536-13
Infusion Equipment for Medical Use – Part 14: Clamps and Flow Regulators for Transfusion and Infusion Equipment without Fluid Contact Positive Pressure Air Leakage Flow Rate with Flow Regulatory – Accuracy Flow Rate with Flow Regulatory – Stability	ISO 8536-14

Test:	Test Method:
Stainless Steel Needle Tubing for the Manufacture of Medical Devices - Requirements and Test Methods	ISO 9626
Stiffness	
Resistance to Breakage	
Resistance to Corrosion	
Medical Connectors Testing – General	ISO 594-1
Gauging	
Liquid Leakage	
Air Leakage	
Separation Force	
Stress Cracking	
Medical Connectors Testing – Lock Fittings	ISO 594-2
Liquid Leakage	
Air Leakage	
Separation Force	
Unscrewing Torque	
Ease of Assembly	
Resistance to Overriding	
Stress Cracking	
Challenging the Device in Safe Mode	ISO 23908
Safety Device Activation Force	ISO 23908
Resistance of the SIPM in Safe Mode to Free Fall	ISO 23908
Dye Leak Penetration	ASTM F1929
Dye Leak, Non-Porous Packaging	ASTM F3039
Bubble Leak	ASTM F2096
Burst	ASTM F1140
Visual Inspection	ASTM F1886
Peel	ASTM F88
Distribution Testing	ASTM D4169
Altitude	ASTM D6653
Drops	ASTM D5276
Dart Impact	ASTM D6344
Bridge Impact	ASTM D5265
Random Vibration	ASTM D4728
Repetitive Shock – Rotary Vibration	ASTM D999

Test:	**Test Method:**
Distribution Testing *(cont'd)*	
Repetitive Shock – Linear Vibration	ASTM D999
Compression	ASTM D642
Performance Testing of Packages for Single Parcel Delivery Systems	ASTM D7386
Packaged Products >150lbs	ISTA 1B, 2B
Packaged Products <150lbs	ISTA 1A, 2A
Extended Testing for Package-Products <150 lbs	ISTA 1C
Extended Testing for Package-Products >150 lbs	ISTA 1D
Unitized Loads of Same Product	ISTA 1E
Packaged-Products <150 lbs (Random Vibration)	ISTA 1G
Packaged-Products >150 lbs (Random Vibration)	ISTA 1H
Packaged-Product for Parcel Delivery System Shipment <150 lbs	ISTA 3A
Packaged Products for Less than Truckload Shipment	ISTA 3B
Unitized Loads for Same Product Truckload	ISTA 3E
Packaged Products in Mixed Pallet Loads for Regional Shipments <100 lbs	ISTA 3F
Temperature Test for Transport Packaging	ISTA 7D
Ships in Own Container (SIOC) for Amazon.com	ISTA 6 Amazon SIOC
e-Commerce Fulfillment for Parcel Delivery Shipment	ISTA-6 Amazon Over Boxing
Environmental Conditioning	
Packages or Packaging Components Temperature: (-70 to 100) °C Humidity: (5 to 95) % RH	ASTM D4332
Packaging Systems for Single Parcel Delivery	ASTM F2825
Accelerated Aging of Sterile Barrier Systems	ASTM F1980

[1] This laboratory also uses customer supplied specifications directly related to the types of tests and within the parameters listed above.

Accredited Laboratory

A2LA has accredited

DDL, INC. – DDL CA

Irvine, CA

for technical competence in the field of

Mechanical Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*. 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*).

Presented this 24th day of February 2025.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3561.02
Valid to May 31, 2027

For the types of tests to which this accreditation applies, please refer to the laboratory's Mechanical Scope of Accreditation.