SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

DDL, INC.
10200 Valley View Road, Suite 101
Eden Prairie, MN 55344
Suzette Glennon Phone: 952 283 2018
Email: suzette.glennon@ddltesting.com

MECHANICAL

Valid To: May 31, 2027 Certificate Number: 3561.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory at the location listed above, as well as the satellite laboratory location listed below, to perform the following types of 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	**Range**
Load	0 to 50 (kN)
Displacement	0 to 35 (in)
Speed	0.04 to 120 (in/min)
Torque	0 to 25 (N·m)
Rotary displacement	0 to 360 (°)
Rotary Speed	0.1 to 60 (rpm)

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

Parameter	**Range**
Load	1000 (lbs)
Acceleration	10G- 600G Drops
Stroke	1-40 (in)
Pulse Types	Square wave (Trapezoidal wave) drops from 10-70 (ms) Half Since Drops from 2 -11 (ms)

Test:	**Test Method[1]:**
Intravascular Catheters – Sterile and Single-use Catheters – Part 1: General Requirements	ISO 10555-1
Corrosion Resistance	
Peak Tensile Force	
Freedom from Leakage- Air Leakage	
Freedom from Leakage- Liquid Leakage	
Flowrate	
Power Injection- Burst	
Power Injection- Flowrate	
Small-bore Connectors for Liquids and Gases in Healthcare Applications – Part 3: Connectors for Enteral Applications	ISO 80369-3
Dimensional Requirements for Enteral for Small Bore Connectors	
Small-bore Connectors for Liquids and Gases in Healthcare Applications – Part 6: Connectors for Neuraxial Applications	ISO 80369-6
Dimensional Requirements for Neuraxia for Small Bore Connectors	
Small-bore Connectors for Liquids and Gases in Healthcare Applications – Part 7: Connectors for Intravascular or Hypodermic Applications	ISO 80369-7
Dimensional Requirements for Luer Connectors	
Small-bore Connectors for Liquids and Gases in Healthcare Applications – Part 20: Common Test Methods	ISO 80369-20
Leakage by Pressure Decay	
Falling Drop Positive-Pressure Liquid Leakage	
Subatmospheric-Pressure Air Leakage	
Stress Cracking	
Resistance to Separation from Axial Load	
Resistance to Separation from Unscrewing	
Resistance to Overriding	
Disconnection by Unscrewing	
Prefilled Syringes – Glass and Plastic Barrels for Injectables and Sterilized Subassembled Syringes Ready for Filing	ISO 11040-4, ISO 11040-6
Closure System Liquid Leakage	
Dye Solution Tightness	
Glide Force	
Luer Lock Adaptor Collar Torque	
Luer Lock Rigid Tip Cap Unscrewing Torque	
Pull-Off Force of the Tip Cap or Needle Shield	
Prefilled Syringes – Glass and Plastic Barrels for Injectables and Sterilized Subassembled Syringes Ready for Filing & Finished Prefilled Syringes	ISO 11040-4, ISO 11040-6, ISO 11040-8
Luer Lock Adaptor Collar Pull-Off Force	
Needle Pull-Out Force	
Flange Breakage Resistance	
Luer Cone Breakage	
Dead Space and Residual Volume	
Needle Penetration	

Test:	**Test Method[1]:**
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
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 from Leakage through Haemostatis Valve Strength of Union of Needle Tube and Needle Hub	ISO 11070
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
Sharps Injury Protection – Requirements and Test Methods − Sharps Protection Features for Single-use Hypodermic Needles, Introducers for Catheters and Needles for Blood Sampling Challenging the Device in Safe Mode Safety Device Activation	ISO 23908
Sterile Hypodermic Needles for Single Use − Requirements and Test Methods Needle Penetration Tolerance on Length Needle Bonding Strength Patency of Lumen	ISO 7864
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

Test:	**Test Method[1]:**
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
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

Test:	**Test Method[1]:**
Infusion Equipment for Medical Use – Part 13: Graduated Flow Regulators for Single Use with Fluid Contact	ISO 8536-13
Positive Pressure Air Leakage	
Vacuum Air Leakage	
Tensile Strength	
Flow Rate with Flow Regulatory – Accuracy	
Flow Rate with Flow Regulatory – Stability	
Infusion Equipment for Medical Use – Part 14: Clamps and Flow Regulators for Transfusion and Infusion Equipment without Fluid Contact	ISO 8536-14
Positive Pressure Air Leakage	
Flow Rate with Flow Regulatory – Accuracy	
Flow Rate with Flow Regulatory – Stability	
Stainless Steel Needle Tubing for the Manufacture of Medical Devices – Requirements and Test Methods	ISO 9626
Stiffness	
Resistance to Breakage	
Resistance to Corrosion	
Sutures - Diameter	USP 861
Sutures – Needle Attachment	USP 871
Sutures – Tensile Strength	USP 881
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	
Dye Leak Penetration	ASTM F1929
Dye Leak, Non-Porous Packaging	ASTM F3039
Bubble Leak	ASTM F2096
Burst	ASTM F1140
Burst with Restraining Plate	ASTM F2054
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

Test:	Test Method[1]:
Random Vibration	ASTM D4728
Repetitive Shock – Rotary Vibration	ASTM D999
Repetitive Shock – Linear Vibration	ASTM D999
Compression	ASTM D642
Impact Test for Pallets	ASTM D880
Shock Tester	ASTM D5487
Mechanical Handling - Pallets	ASTM D6055
Fork Lift Drops/Tip Test - Pallets	ASTM D6179
Performance Testing of Packages for Single Parcel Delivery Systems	ASTM D7386
Package-Products <150 lbs	ISTA 1A
Package-Products >150 lbs	ISTA 1B
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
Package-Products <150 lbs	ISTA 2A
Package-Products >150 lbs	ISTA 2B
Furniture Packages	ISTA 2C
Packaged-Product for Parcel Delivery System Shipment <150 lbs	ISTA 3A
Packaged Products for Less Than Truckload	ISTA 3B
Unitized Loads of Same Product	ISTA 3E
Packaged Products for Distribution Center to Retail Outlet Shipment 100lb	ISTA 3F
Products or packaged Products in Mechanically Handled Bulk Transport Container	ISTA 3H
Packaged Products for Shipment in known Distribution Channels	ISTA 4AB
Packaged Products for Sam's Club Distribution Shipments	6-Sam’s Club
Heavy/Bulky Packaged Product for Amazon Distribution Shipments	6-Amazon.com-B
Ships in Own Container (SIOC) for Amazon.com	ISTA-6 Amazon.com SIOC
e-Commerce Fulfillment for Parcel Delivery Shipment	ISTA-6 Amazon.com Over Boxing
Environmental Conditioning	
Packages or Packaging Components	ASTM D4332
Packaging Systems for Single Parcel Delivery	ASTM F2825
Accelerated Aging of Sterile Barrier Systems	ASTM F1980
Plastics	ASTM D618
Complete, Filled Transport Packages and Unit Loads	ISO 2233
Temperature Test for Transport Packaging	ISTA 7D, ISTA 2A

Dimensional Testing

Parameter/Equipment	Range	CMC[2,3,4]	Comment
Volume[5] – (X, Y, Z) Measure	700 mm x 270 mm x 270 mm	(9.3 + 11*L*) µm	Zeiss Metrotom 800 CT

DDL, INC.
5411 Opportunity Court
Minnetonka, MN 55343

Test:
Temperature and Humidity:
Temperature Range: (-65 to 120) °C;
Humidity Range: RH (5 to 95) %

Test Method[1]:
ASTM F1980, ASTM F2825, ASTM D618, D4332; ISTA 7D, ISTA 2A; ISO 2233

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

[2] Calibration and Measurement Capability Uncertainty (CMC) is the smallest uncertainty of measurement that a laboratory can achieve within its scope of accreditation when performing more or less routine calibrations of nearly ideal measurement standards or nearly ideal measuring equipment. CMCs represent expanded uncertainties expressed at approximately the 95 % level of confidence, usually using a coverage factor of $k = 2$. The actual measurement uncertainty of a specific calibration performed by the laboratory may be greater than the CMC due to the behavior of the customer's device and to influences from the circumstances of the specific calibration.

[3] In the statement of CMC L is the measured length in meters.

[4] The type of instrument or material being tested is defined by the parameter. This indicates the laboratory is capable of testing instruments that measure or generate the values in the ranges indicated for the listed measurement parameter.

[5] This test is not equivalent to that of a calibration.

Accredited Laboratory

A2LA has accredited

DDL, INC.

Eden Prairie, MN

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 3rd day of March 2025.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3561.01
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.