



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

DDL, INC.
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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 Sine Drops from 2 -11 (ms)

Test:**Test Method¹:**

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 Method¹:**

Prefilled Syringes – Requirements and Test Methods for Finished Prefilled Syringes

ISO 11040-8

- Deliverable Volume
- Break Loose Extrusion Force (BLEF)
- Dose Accuracy
- Burst Resistance
- Markings
- Liquid Leakage Beyond the Plunger

Sterile Single Use Intravascular Introducers, Dilators, and Guidewires

ISO 11070

- 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

Needle – Base Injection Systems for Medical Use – Requirements and Test Methods – Part 1: Needle Based Injection Systems

ISO 11608-1

- Environmental Conditioning
- Free Fall Testing
- Vibration Testing
- Dose Accuracy

Sharps Injury Protection – Requirements and Test Methods – Sharps Protection Features for Single-use Hypodermic Needles, Introducers for Catheters and Needles for Blood Sampling

ISO 23908

- Challenging the Device in Safe Mode
- Safety Device Activation

Sterile Hypodermic Needles for Single Use – Requirements and Test Methods

ISO 7864

- Needle Penetration
- Tolerance on Length
- Needle Bonding Strength
- Patency of Lumen

Sterile Hypodermic Syringes for Single Use – Syringes for Manual Use

ISO 7886-1

- Graduated Capacity and Dead Space
- Graduated Scale
- Barrel
- Plunger Stopper/ Plunger Assembly
- Nozzle
- Performance

Test:**Test Method¹:**

Infusion Equipment for Medical Use – Part 4: Infusion Sets for Single Use, Gravity Feed

ISO 8536-4

- 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

Infusion Equipment for Medical Use – Part 8: Infusion Sets for Single Use with Pressure Infusion Equipment

ISO 8536-8

- 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

Infusion Equipment for Medical Use – Part 9: Fluid Lines for Single Use with Pressure Infusion Equipment

ISO 8536-9

- Positive Pressure Air Leakage
- Positive Pressure Liquid Leakage
- Tensile Strength
- Storage Volume

Infusion Equipment for Medical Use – Part 10: Accessories for Fluid Lines for Single Use with Pressure Infusion Equipment

ISO 8536-10

- Positive Pressure Air Leakage
- Positive Pressure Liquid Leakage
- Tensile Strength
- Injection Site

Infusion Equipment for Medical Use – Part 11: Infusion Filters for Single Use with Pressure Infusion Equipment

ISO 8536-11

- Positive Pressure Air Leakage
- Positive Pressure Liquid Leakage
- Tensile Strength

Infusion Equipment for Medical Use – Part 12: Check Valves for Single Use

ISO 8536-12

- Positive Pressure Air Leakage
- Positive Pressure Liquid Leakage
- Vacuum Air Leakage
- Blocking Performance
- Opening Pressure
- Flow Rate of Infusion Set

Test:**Test Method¹:**

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 Method¹:**

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
FEDEX Procedure for Testing Packaged Products <150	ISTA 6-FEDEX-A
FEDEX Procedure for Testing Packaged Products >150	ISTA 6-FEDEX-B
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 + 11L) µm	Zeiss Metrotom 800 CT

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Test:

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

Test Method¹:

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.

A blue ink signature of Mr. Trace McInturff, written over a horizontal line.

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.