



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

DDL, INC.¹
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MECHANICAL

Valid To: May 31, 2023

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 two satellite laboratory locations listed below 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:

<u>Parameter</u>	<u>Range (Units)</u>
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)

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 Load
- Resistance to Separation from Unscrewing
- Resistance to Overriding
- Disconnection by Unscrewing

ISO 80369-20

Prefilled Syringes- Glass and Plastic Barrels for
Injectables and Sterilized Sub assembled 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

Test

Test Method

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

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

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

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



Test**Distribution Testing**

Altitude

Drops

Dart Impact

Bridge Impact

Random Vibration

Repetitive Shock – Rotary Vibration

Repetitive Shock – Linear Vibration

Compression

Impact Test for Pallets

Shock Tester

Mechanical Handling - Pallets

Fork Lift Drops/Tip Test - Pallets

Performance Testing of Packages for Single

Parcel Delivery Systems

Package-Products <150 lbs

Package-Products >150 lbs

Extended Testing for Package-Products <150 lbs

Extended Testing for Package-Products >150 lbs

Unitized Loads of Same Product

Packaged-Products <150 lbs (Random Vibration)

Packaged-Products >150 lbs (Random Vibration)

Package-Products <150 lbs

Package-Products >150 lbs

Furniture Packages

Packaged-Product for Parcel Delivery System

Shipment <150 lbs

Packaged Products for Less Than Truckload

Unitized Loads of Same Product

Packaged Products for Distribution Center to

Retail Outlet Shipment 100lb

Products or packaged Products in Mechanically

Handled Bulk Transport Container

Packaged Products for Shipment in known

Distribution Channels

Packaged Products for Sam's Club Distribution

Shipments

Heavy/Bulky Packaged Product for Amazon

Distribution Shipments

Ships in Own Container (SIOC) for Amazon.com

e-Commerce Fulfillment for Parcel Delivery

Shipment

FEDEX Procedure for Testing Packaged

Products <150

FEDEX Procedure for Testing Packaged

Products >150

Test Method

ASTM D4169

ASTM D6653

ASTM D5276

ASTM D6344

ASTM D5265

ASTM D4728

ASTM D999

ASTM D999

ASTM D642

ASTM D880

ASTM D5487

ASTM D6055

ASTM D6179

ASTM D7386

ISTA 1A

ISTA 1B

ISTA 1C

ISTA 1D

ISTA 1E

ISTA 1G

ISTA 1H

ISTA 2A

ISTA 2B

ISTA 2C

ISTA 3A

ISTA 3B

ISTA 3E

ISTA 3F

ISTA 3H

ISTA 4AB

6-Sam's Club

6-Amazon.com-B

ISTA-6 Amazon.com SIOC

ISTA-6 Amazon.com Over Boxing

ISTA 6-FEDEX-A

ISTA 6-FEDEX-B

<u>Test</u>	<u>Test Method</u>
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

¹This accreditation also covers testing performed at the following satellite laboratories listed below:

DDL, INC.²
5411 Opportunity Court
Minnetonka, MN 55343

<u>Test</u>	<u>Test Method</u>
Temperature and Humidity:	ASTM F1980, ASTM F2825, ASTM D618, D4332; ISTA 7D, ISTA 2A; ISO 2233
Temperature Range: (-65 to 120) °C;	
Humidity Range: RH (5 to 95) %	

DDL, INC.²
5405 Opportunity Court
Minnetonka, MN 55343

<u>Test</u>	<u>Test Method</u>
Temperature and Humidity	ASTM F1980
Temperature Range: (-23 to 45) °C	
Humidity Range: RH (50 to 75) %	

²This 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.

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 19th day of May 2021.

A blue ink signature of the Vice President of Accreditation Services.

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3561.01
Valid to May 31, 2023

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