



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

DDL, INC.
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MECHANICAL

Valid To: May 31, 2025

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:

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

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

Test:

Test Method:

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
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
FEDEX Procedure for Testing Packaged Products <150 lbs	ISTA 6-FEDEX-A
FEDEX Procedure for Testing Packaged Products >150lbs	ISTA- 6 FEDEX - B
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	ASTM D4332
Temperature: (-45 to 100) °C	
Humidity: (10 to 95) % RH	
Packaging Systems for Single Parcel Delivery	ASTM F2825
Accelerated Aging of Sterile Barrier Systems	ASTM F1980





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 19th day of May 2023.

A blue ink signature of Trace McInturff, Vice President of Accreditation Services.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3561.02
Valid to May 31, 2025



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