



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

DDL, INC.
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MECHANICAL

Valid To: May 31, 2023

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:

Test:

Test Method:

Small-bore Connectors for Liquids and Gases in Healthcare Applications

ISO 80369-20

– 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

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

(A2LA Cert. No. 3561.02) Revised 03/08/2022

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Test:

Test Method:

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
Repetitive Shock – Linear Vibration	ASTM D999
Compression	ASTM D642
Performance Testing of Packages for Single Parcel Delivery Systems	ASTM D7386
Packaged-Product for Parcel Delivery System Shipment <150 lbs	ISTA 3A
Extended Testing for Package-Products <150 lbs	ISTA 1C
Packaged-Products <150 lbs	ISTA 1A, 2A
Packaged-Products <150 lbs (Random Vibration)	ISTA 1G
FEDEX Procedure for Testing Packaged Products <150 lbs	ISTA 6-FEDEX-A
Temperature Test for Transport Packaging	ISTA 7D
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 2021.

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

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3561.02
Valid to May 31, 2023



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