SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

DDL MN2
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MECHANICAL

Valid To: March 31, 2027 Certificate Number: 3561.04

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory at the location listed above to perform the following tests:

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

Parameter	**Range**
Load	0 to 2kN
Displacement	0 to 890 mm (35 inches)
Speed	1 mm/ min to 2500 mm/ min
Torque	0 to 25 N·m Torque
Rotary Displacement	0 to 360 (º)
Rotary Speed	0.1 to 60 (rpm)

Test	**Test Method [1]**
Prefilled Syringes – Glass and Plastic Barrels for Injectables and Sterilized Subassembled Syringes ready for Filling Closure System and Liquid Leakage Dye Solution Tightness Glide Force Pull off Force of the Tip and Cap or Needle Shield	ISO 11040-4; ISO 11040-6
Prefilled Syringes – Glass and Plastic Barrels for Injectables and Sterilized Subassembled Syringes Ready for Filling and Finished Prefilled Syringes Luer lock Adaptor Collar Pull Off Force Needle Pull Out Forces Flange Breakage Resistance Luer Cone Breakage Dead Space and Residual Volume Needle Penetration Luer Lock Adaptor Collar Torque Luer Lock Rigid Tip Cap Unscrewing	ISO 11040-4; ISO 11040-6; ISO 11040-8

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
Sharps Injury Protection- Requirements and Test Methods- Sharps Protection Features for Single use Hypodermic Needles, Introducers for Catheters and Needles and Blood Sampling Challenging the Device in Safe Mode Safety Device Activation Resistance of the SIPM in Safe Mode to Free Fall	ISO 23908
Needle based injection systems for medical use- Requirements and Test Methods Part 1: Needle Based Injection Systems Environmental Conditioning Dose Accuracy Free Fall Testing Vibration Testing (3 - 4000 Hz, Max Payload 400 lbs)	ISO 11608-1
Needle-based injection systems for medical use – Requirements and test methods – Part 5: Automated functions	ISO 11608-5
Elastomeric Component Functional Suitability in Parenteral Product Packaging Delivery Systems Break-Loose and Extrusion Force Penetration Force Plunger Seal Integrity Spike Retention and Sealability Tip Cap and Needle Shield Functional Suitability – Axial Tip Cap and Needle Shield Functional Suitability – Torque	USP 382
Temperature and Humidity Temperature Range: -45 C to 120 C Humidity Range: RH 10% to 95%	ASTM F1980; ASTM F2825; ASTM D618; ASTM D4332
Distribution Testing	ASTM D4169
Altitude	ASTM D6653
Drops	ASTM D5276
Dart Impact	ASTM D6344
Bridge Impact	ASTM D5265
Random Vibration	ASTM D4728

Test	Test Method [1]
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
Package-Products <150 lbs	ISTA 1A
Extended Testing for Package-Products <150 lbs	ISTA 1C
Packaged-Products <150 lbs (Random Vibration)	ISTA 1G
Package-Products <150 lbs	ISTA 2A
Packaged-Product for Parcel Delivery System Shipment <150 lbs	ISTA 3A
Packaged Products for Distribution Center to Retail Outlet Shipment 100lb	ISTA 3F

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

Accredited Laboratory

A2LA has accredited

DDL MN2

Minnetonka, 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 24th day of February 2025.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3561.04
Valid to March 31, 2027

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