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 in accordance with Good Laboratory Practices (GLP) Regulations per 21 CFR 58, 210, 211, and 820:

Test	Test Method [1]
Prefilled Syringes – Glass and Plastic Barrels for Injectables and Sterilized Subassembled Syringes ready for Filing 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 Filing 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	ISO 11040-4; ISO 11040-6; ISO 11040-8
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

Test	Test Method [1]
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	ISO 23908
Needle based injection systems for medical use- Requirements and Test Methods Part 1: Needle Based Injection Systems Environmental Conditioning Dose Accuracy	ISO 11608-1
Temperature and Humidity Temperature Range: -45 C to 120 C Humidity Range: RH 10% to 95%	ASTM F1980; ASTM F2825; ASTM D618; ASTM D4332

[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.