

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Affinity Biologicals Inc.

(FIN F006797)

Main Site: 1348 Sandhill Drive

Ancaster, Ontario, L9G 4V5, Canada

has been registered by Intertek, an MDSAP recognized auditing organization,
as conforming to the requirements of:

ISO 13485:2016

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

The management system is applicable to:

The registration covers the Quality Management System for the design, development, manufacture and distribution of in vitro diagnostic test kits and reagents used in the detection and management of coagulation disorders including laboratory use in vitro diagnostic devices.

Certificate Number:

0152755

Revision Level: 00

Initial Certification Date:

2019-02-28

Certification Effective Date:

2023-07-02

Certification Expiry Date:

2025-02-26



intertek

A handwritten signature in black ink, appearing to read "Calin Moldovean", is written over a horizontal line.

Calin Moldovean

President, Business Assurance

Intertek Testing Services NA, Inc.
900 Chelmsford Street
Lowell, MA, USA 01851

