ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

C E R T I F I C A T E

No. QS6 125906 0001 Rev. 01

Certificate Holder: **Affinity Biologicals Inc.**
1348 Sandhill Drive
Ancaster ON L9G 4V5
CANADA

Certification Mark:

Scope of Certificate: **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**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Health Canada, USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 125906 0001 Rev. 01
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F007468**
Report No.: **7169015459**
Effective Date: **2025-02-27**
Expiry Date: **2028-02-26**

Date of Issue: 2025-02-17

(Renee Walker)
Director, US Certification Body, MHS

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Regulatory Requirements: **Audit/Certification Criteria**

Canada
- Medical Device Regulations – Part 1- SOR 98/282

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies): **Affinity Biologicals Inc.**
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