CERTIFICATE

No. QS6 113961 0003 Rev. 00

Certificate Holder:

Alba Bioscience Limited
5 James Hamilton Way
Milton Bridge, Penicuik, EH26 0BF
UNITED KINGDOM

Certification Mark:

TÜV
SÜD
ISO 13485

Scope of Certificate:

**Design, Development, Manufacture and Distribution
of In-Vitro Diagnostic Reagents for Use in Manual
and Automated Immunohaematology and Infectious
Immunology Testing**

Standard(s): ISO 13485:2016

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, 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. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: F006227

Effective Date: 2023-02-07

Expiry Date: 2026-02-06

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Date of Issue: 2023-03-03

(Renee Walker)
Director, US Certification Body, MHS

TÜV SÜD
America

C E R T I F I C A T E
No. QS6 113961 0003 Rev. 00

Regulatory Requirements:	**Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002 - Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

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):
Alba Bioscience Limited
5 James Hamilton Way, Milton Bridge, Penicuik, EH26 0BF, UNITED KINGDOM

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