




# CERTIFICATE

No. QS6 123789 0006 Rev. 00

**Certificate Holder:** **Lorne Laboratories Ltd**  
Unit 1 Cutbush Park Industrial Estate  
Danehill  
Lower Earley, Berkshire RG6 4UT  
UNITED KINGDOM

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production and Distribution of In-Vitro Diagnostic Reagents for Immunohaematology (Blood Grouping)**

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

**Regulatory Authority(ies):** **Brazil ANVISA, Health Canada. 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\\_123789\\_0006\\_Rev.00](http://www.tuvsud.com/ps-cert?q=cert:QS6_123789_0006_Rev.00)

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**REPs Facility ID:** **F008812**  
**Report No.:** **75966237**  
**Effective Date:** **2026-05-08**  
**Expiry Date:** **2029-05-07**



( Renee Walker )  
Director, US Certification Body, MHS

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**Regulatory Requirements:    Audit/Certification Criteria**

**Brazil**

- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

**Canada**

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

**Facility(ies):**

**Lorne Laboratories Ltd**

Unit 1 Cutbush Park Industrial Estate, Danehill, Lower Earley,  
 Berkshire RG6 4UT, UNITED KINGDOM

**Facility Scopes:**

Design and Development, Production and Distribution of In-Vitro  
 Diagnostic Reagents for Immunohaematology (Blood Grouping)

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Date of Issue: 2026-05-13



( Renee Walker )  
 Director, US Certification Body, MHS