



**Solutions**

# CERTIFICATE OF REGISTRATION

## Lorne Laboratories Ltd

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

Facility ID: F001410

UL Medical Regulatory Services of UL LLC® (UL Solutions) issues this certificate to the Firm named above, after auditing the Firm's quality management system and finding it in conformance per the defined scope with respect to:

**ISO 13485:2016**

**EN ISO 13485:2016**

with additional regulatory requirements listed on final page of this certificate.

The design and manufacture of in vitro diagnostic reagents for the detection of the blood groups.

Authorized by



**Paul Hilgeman**  
Senior Business Manager - Medical  
CMIT – Medical Regulatory



Check Certificate Status:  
[here](#)

File Number	A12241	Cycle Start Date	May 23, 2023
Certificate Number	1459.230523	Effective Date	May 23, 2023
Initial Issue Date	June 26, 2018	Expiry Date	May 22, 2026

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL Medical and Regulatory Services of UL LLC® (UL Solutions). Certificates may be verified by visiting the Online Certifications Directory on UL.com.



**UL Medical and Regulatory  
Services UL, LLC is an  
MDSAP Recognized  
Auditing Organization**

UL Solutions  
333 Pfingsten Road  
Northbrook, IL 60062-2096 USA



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### Additional Regulatory Requirements

**Brazil:**

- RDC ANVISA n. 665/2022
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009

**Canada:**

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

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