

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.

MDSAP MEDICAL DEVICE SUNGLE AUDIT PROGRAM Authorized by

Paul Hilgeman Senior Business Manager - Medical

CMIT – Medical Regulatory

Camp By Printers (i)

Check Certificate Status:

<u>here</u>

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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