CERTIFICATE OF REGISTRATION

Lorne Laboratories Ltd

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

REPs Facility ID: F001410

UL Medical Regulatory Services of UL LLC®(UL) 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

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 SINGLE AUDIT PROGRAM

Authorized by

Michael J. Windler, P.E.
Manager of Global Regulatory Service
Distinguished Member of the Technical Staff
UL Life and Health Sciences
UL LLC

Check Certificate Status: here

File Number	A12241	Cycle Start Date	May 23, 2020
Certificate Number	1459.200523	Effective Date	May 23, 2020
Initial Issue Date	June 26, 2018	Expiry Date	May 22, 2023

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.
Certificates may be verified by visiting the Online Certifications Directory on UL.com.

UL REGISTERED FIRM

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

Digitally signed by Ceaicovschi Tudor
Date: 2023.02.09 10:38:33 EET
Reason: MoldSign Signature
Location: Moldova

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

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Additional Regulatory Requirements

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

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

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

CERTIFICATE

EC No 1434-IVDD-133/2019
EC Design-Examination

Directive 98/79/EC on in vitro diagnostic medical devices

Polish Centre for Testing and Certification certifies
that manufactured by:

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate, Danehill, Lower Earley, Berkshire RG6 4UT, United Kingdom

in vitro diagnostic medical devices
List A

Products list in attachments: 1

in terms of design documentation, comply with requirements of Annex IV section 4 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 10.04.2019 to 23.05.2023

The date of issue of the Certificate: 10.04.2019

The date of the first issue of the Certificate: 10.04.2019

CE 1434

Application No: 649/2019
Module: H6

mgr Anna Wyroba
Vice-President

Certificate No **1434-IVDD-133/2019**
Issued under the Contract No MD-59/2019
Bears the PCBC hologram.
Warsaw, 10.04.2019

ANNEX 1 TO CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-133/2019

The products detailed below are covered under the scope of this certificate:

Name:	GMDN code:
Anti-A Monoclonal, 600010	52532
Anti-B Monoclonal, 610010	52538
Anti-A,B Monoclonal, 620010	46442
Anti-D Clone 1 Monoclonal, 730010	52647
Anti-D Clone 2 Monoclonal, 710010	52647
Anti-D Duoclone Monoclonal, 740010	52647
Anti-C Monoclonal, 690005	52546
Anti-E Monoclonal, 691005	52562
Anti-c Monoclonal, 692005	52547
Anti-e Monoclonal, 693005	52563
Anti-C+D+E Monoclonal, 700010	52550
Anti-K Monoclonal, 760010	52593

CE 1434

mgr Anna Wyroba
Vice-President

Annex 1 to certificate No. **1434-IVDD-133/2019**
Issued under the Contract No. MD-59/2019
Bears the PCBC hologram.
Warsaw, 10.04.2019