

### **EC DECLARATION OF CONFORMITY**

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product Name	Catalogue Number
Anti-A₁ Lectin	116005

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

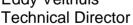
and is in conformity with the national standards transposing harmonised standards:

- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 15223-1:2016
- BS EN ISO 18113-2:2011
- BS EN ISO 23640:2015

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 04 April 2017.

**Eddy Velthuis** 





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



### **CERTIFICATE OF REGISTRATION**

#### **Lorne Laboratories Ltd**

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

UL LLC® (UL Solutions) issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in compliance with:

ISO 13485:2016 EN ISO 13485:2016

The design and manufacture of in vitro diagnostic blood grouping reagents. The purchase for resale of in vitro diagnostic serology test kits.

UKAS MANAGEMENT SYSTEMS
4426

Authorized by

Paul Hilgeman
Senior Business Manager - Medical
CMIT – Medical Regulatory

Can Physica (i)

Check Certificate Status: here

File Number A12241 Cycle Start May 23, 2023
Certificate Number 1458.230523 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 LLC® (UL Solutions).



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



## **EC Certificate No. 1434-IVDD-075/2022**

**Full Quality Assurance System** Directive 98/79/EC concerning in vitro diagnostic medical devices

Polish Centre for Testing and Certification certifies that the quality assurance system in the organization:

# **Lorne Laboratories Ltd**

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

for the design, manufacture and final inspection of in vitro diagnostic medical device

The list of medical devices covered by this certificate is provided in the Annex 1 to EC Design-examination Certificate No. 1434-IVDD-074/2022

> complies with requirements of Annex IV (excluding Section 4, 6) to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 28.04.2022 to 27.05.2025

The date of issue of the Certificate: 28.04.2022

The date of the first issue of the Certificate: 10.04.2019



Issued under the Contract No. MD-004/2022 Application No: 505/2022 Certificate bears the qualified signature. Warsaw, 28/04/2022 Module H7

**President**