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

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).

Digitally signed by Ceaicovschi Tudor
Date: 2024.11.07 11:24:19 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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

LORNE LABORATORIES LIMITED	Document Title:	**EU Declaration of Conformity**
Date Effective: **02 Oct 2019**	Document Number:	**DoCSyphilis**
DCN: **999**	Revision Number:	**01**

Lorne Laboratories Ltd declares that the product family **Syphilis** comprises of the following in vitro diagnostic reagents:

Product Name	Catalogue Number	GMDN Number
TPHA Microtitre Plate kit	043100A	51800
RPR Carbon kit	044150A / 044500A	51819
RPR Carbon Antigen	045005A	51819
VDRL Stabilised Reagent kit	046511A	51819
RPR Carbon Positive Control	047001A	32449

have been classified as non List A, non List B (Directive 98/79/EC, Annex II) and comply with the essential requirements and provisions of the European Communities Council Directive 98/79/EC concerning In-Vitro Diagnostic Medical Devices as amended by Regulation (EC) 596/2009 and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

The Intended Purpose of these products is to identify and quantitate specific antibodies in human sera following infection with syphilis which should only be carried out by suitably trained professionals.

The manufacturer of these products is Lorne Laboratories Ltd who is located at:

Address line 1: Unit 1 Cutbush Park Industrial Estate
Address line 2: Danehill
City: Lower Earley
County: Berkshire
Postal code: RG6 4UT
Country: United Kingdom
Telephone number: +44-(0)118 921 2264
Fax number: +44-(0)118 986 4518
Website: www.lornelabs.com
DUNS Number: 732670703

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

- BS EN ISO 13485:2016
- 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.

Lorne's EU Authorised Representative is "Advena Limited" residing at Tower Business Centre, 2nd Floor, Tower Street, Swatar BKR 4013 Malta.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 02 October 2019.

Eddy Velthuis
Technical Director