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 SINGLE AUDIT PROGRAM

Authorized by

Paul Hilgeman
Senior Business Manager - Medical
CMIT – Medical Regulatory

Check Certificate Status:
here

Digitally signed by Ceaicovschi Tudor
Date: 2023.06.07 11:53:56 EEST
Reason: MoldSign Signature
Location: Moldova

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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Unit 1 Cutbush Park Industrial Estate
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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

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

CERTIFICATE

EC Certificate No. 1434-IVDD-027/2022

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
List B

The list of medical devices covered by this certificate is provided in the Annex 1

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 23.03.2022 to 27.05.2025

The date of issue of the Certificate: 03.03.2022

The date of the first issue of the Certificate: 10.04.2019

CE 1434

Issued under the Contract No. MD-173/2021
Application No: 577/2022
Certificate bears the qualified signature.
Warsaw, 03/03/2022
Module H7

Aleksandra Kostrzewa

Digitally signed by Aleksandra Kostrzewa

President

ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-027/2022

List of medical devices covered by the certificate:

Anti-Jka Polyclonal 323002
Anti-Jkb Polyclonal 324002
Anti-Fyb Polyclonal 317002
AHG Elite Clear 415010
AHG Elite Green 435010
Anti-Fya Monoclonal 774002
Anti-Human IgG Clear 401010
Anti-Human IgG Green 402010
Anti-Jka Monoclonal 775002
Anti-Jkb Monoclonal 776002

CE 1434

Issued under the Contract No. MD-173/2021
Application No: 577/2021
Certificate bears the qualified signature.
Warsaw, 03/03/2022

Aleksandra Kostrzewa

Digitally signed by Aleksandra Kostrzewa

President

SAFETY DATA SHEET

Document reference number: MSDS460/470
Issue number: 3/08/2015

ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830

1. SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product code(s) & Product Name	460 LISS Concentrate 470 LISS Ready for Use
CAS No.	Mixture
EINECS No.	Mixture
Product Description	A clear, colourless solution containing 0.1% sodium azide (LISS Concentrate) or 0.01% sodium azide (LISS Ready for Use), Glycine and Sodium salts.

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified Use(s)	Potentiating agent in blood group serology.
Uses Advised Against	Anything other than the above.

1.3 Details of the supplier of the safety data sheet

Company Identification	Lorne Laboratories Ltd Unit 1 Cutbush Park Industrial Estate Danehill Lower Earley Berkshire RG6 4UT United Kingdom
Telephone	+44(0) 0118 921 2264
Fax	+44(0) 0118 986 4518
E-Mail (competent person)	Info@lornelabs.com

1.4 Emergency telephone number

	+44(0) 0118 921 2264 Available 0900 – 1700 (GMT)
Languages spoken	English

2. SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

2.1.1 Regulation (EC) No. 1272/2008 (CLP) Not classified as hazardous for supply/use.

2.2 Label elements According to Regulation (EC) No. 1272/2008 (CLP)

Hazard Pictogram(s)	None assigned
Signal Word(s)	None assigned
Hazard Statement(s)	None assigned
Precautionary Statement(s)	None assigned

2.3 Other hazards None known.

3. SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures Substances in preparations / mixtures

EC Classification Regulation (EC) No. 1272/2008 (CLP)

Chemical identity of the substance	%W/W	CAS No.	EC No.	REACH Registration No.	Hazard Statement(s)
Sodium Azide	0.1 - 0.01	26628-22-8	247-852-1	Not yet assigned in the supply chain	Acute Tox. 2; H300 Aquatic Acute 1; H400 Aquatic Chronic 1; H410

4. SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation	Remove from exposure. Remove victim to fresh air and keep at rest in a position comfortable for breathing. Keep warm and at rest. Get medical advice/attention if you feel unwell.
Skin Contact	Wash affected skin with soap and water. Remove contaminated clothing and wash clothing before reuse. If irritation (redness, rash, blistering) develops, get medical attention.
Eye Contact	Flush eyes with water for at least 15 minutes while holding eyelids open. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention.
Ingestion	Rinse mouth. Give plenty of water to drink. Do not give anything by mouth to an unconscious person. Get medical advice/attention if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed — None known.

4.3 Indication of any immediate medical attention and special treatment needed — Treat symptomatically.

5. SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing Media	Non-flammable. As appropriate for surrounding fire. Water spray, foam, dry powder or CO2.
Unsuitable extinguishing Media	Do not use water jet. Direct water jet may spread the fire.

5.2 Special hazards arising from the substance or mixture — Combustion or thermal decomposition will evolve toxic vapours.

5.3 Advice for fire-fighters — Fight fire with normal precautions from a reasonable distance. Fire fighters should wear complete protective clothing including self-contained breathing apparatus. Avoid all contact. Do not allow run-off from fire fighting to enter drains or water courses.

6. SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures — Ensure adequate ventilation. Avoid all contact. Ensure suitable personal protection during removal of spillages. See Section: 8

6.2 Environmental precautions — Avoid release to the environment.

6.3 Methods and material for containment and cleaning up — Absorb spillage in suitable inert material.Transfer to a lidded container for disposal or recovery. Ventilate the area and wash spill site after material pick-up is complete. Avoid release to the environment.

6.4 Reference to other sections — See Section: 8, 13

7. SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling — Avoid all contact. Use personal protective equipment as required. Ensure adequate ventilation. Keep good industrial hygiene. Wash hands thoroughly after handling. Contaminated clothing should be thoroughly cleaned.

7.2 Conditions for safe storage, including any incompatibilities — Keep only in the original container/package in a well-ventilated place. Keep away from food, drinks and animal food.

Storage temperature	Storage temperature is at ambient room temperature.
Storage life	Keep only in the original container/package in a well-ventilated place.
Incompatible materials	None known.

7.3 Specific end use(s) — See Section: 1.2

8. SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1	**Occupational Exposure Limits**	None assigned.
8.1.2	**Biological limit value**	Not established.
8.1.3	**PNECs and DNELs**	Not established.

8.2 Exposure controls

8.2.1	**Appropriate engineering controls**	Ensure adequate ventilation. Good hygiene practices and housekeeping measures.
8.2.2	**Individual protection measures, such as personal protective equipment (PPE)**	Use personal protective equipment as required. Avoid all contact. Keep good industrial hygiene. Wash hands before breaks and after work. Keep work clothes separately. Wash contaminated clothing before reuse. Do not eat, drink or smoke at the work place.
	Eye/face protection 	Not normally required. Recommended: Wear eye protection with side protection (EN166).
	Skin protection 	Prolonged, direct contact: Wear impervious gloves (EN374).
	Respiratory protection 	Not normally required. In case of insufficient ventilation, wear suitable respiratory equipment. Respiratory protective equipment should conform to the appropriate EN standard.
	Thermal hazards	None anticipated.
8.2.3	**Environmental Exposure Controls**	Avoid release to the environment.

9. SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Liquid, colourless
Odour	Not established.
Odour Threshold	Not established.
pH	6.7
Melting Point/Freezing Point	Not established.
Initial boiling point and boiling range	Not established.
Flash Point	Not established.
Evaporation Rate	Not established.
Flammability (solid, gas)	Not established.
Upper/lower flammability or explosive limits	Not applicable.
Vapour pressure	Not established.
Vapour density	Not established.
Relative density	Not established.
Solubility(ies)	Miscible with water.
Partition coefficient: n-octanol/water	Not established.
Auto-ignition temperature	Not established.
Decomposition Temperature	Not established.
Viscosity	Not established.
Explosive properties	Not explosive

	Oxidising properties	Not oxidising.
9.2	**Other information**	None known.

10. SECTION 10: STABILITY AND REACTIVITY

10.1	**Reactivity**	Stable under normal conditions.
10.2	**Chemical stability**	Stable for 12 months after the date of production when stored at ambient room temperature.
10.3	**Possibility of hazardous reactions**	None known. Hazardous polymerisation will not occur.
10.4	**Conditions to avoid**	Keep away from heat, sources of ignition and direct sunlight.
10.5	**Incompatible materials**	Strong acids, strong oxidizing agents.
10.6	**Hazardous decomposition product(s)**	Combustion or thermal decomposition will evolve toxic vapours.

11. SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects (Substances in preparations / mixtures)

Acute toxicity

Ingestion	Based on available data, the classification criteria are not met. Acute Toxicity Estimate Mixture Calculation: LD50 >2000 mg/kg bw/day
Inhalation	Based on available data, the classification criteria are not met. Acute Toxicity Estimate Mixture Calculation: LD50 >20 mg/l.
Skin Contact	Based on available data, the classification criteria are not met. Acute Toxicity Estimate Mixture Calculation: LD50 >2000 mg/kg bw/day
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Serious eye damage/irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

11.2	**Other information**	None known.

12. SECTION 12: ECOLOGICAL INFORMATION

12.1	**Toxicity**	Based on available data, the classification criteria are not met. Estimated LC50 (96 hour) Fish > 100 mg/l
12.2	**Persistence and degradability**	Not established. Some of the ingredients are expected to be resistant to biodegradation.
12.3	**Bioaccumulative potential**	Not established. Predicted to be be unlikely.
12.4	**Mobility in soil**	The product has high mobility in soil. Miscible with water.
12.5	**Results of PBT and VPVB assessment**	Not classified as PBT or vPvB. None of the substances in this product fulfil the criteria for being regarded as a PBT or vPvB substance.
12.6	**Other adverse effects**	None known.

13. SECTION 13: DISPOSAL CONSIDERATIONS

13.1	**Waste treatment methods**	Disposal should be in accordance with local, state or national legislation.
13.2	**Additional Information**	Empty containers may contain hazardous residues. Containers shall be disposed of by incineration as soon as possible.

14. SECTION 14: TRANSPORT INFORMATION

Not classified according to the United Nations 'Recommendations on the Transport of Dangerous Goods'.

		ADR/RID	IMDG	IATA/ICAO
14.1	**UN number**	None assigned.	None assigned.	None assigned.
14.2	**UN proper shipping name**	None assigned.	None assigned.	None assigned.
14.3	**Transport hazard class(es)**	None assigned.	None assigned.	None assigned.
14.4	**Packing group**	None assigned.	None assigned.	None assigned.
14.5	**Environmental hazards**	Not classified.	Not classified.	Not classified.
14.6	**Special precautions for user**	See Section: 2		
14.7	**Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.	Not applicable.	Not applicable.
14.8	**Additional Information**	None.		

15. SECTION 15: REGULATORY INFORMATION

15.1	**Safety, health and environmental regulations/legislation specific for the substance or mixture**	
15.1.1	**EU regulations**	
	Authorisations and/or Restrictions On Use	None.
15.1.2	**National regulations**	
	Germany	Water hazard class: 1
15.2	**Chemical Safety Assessment**	None.

16. SECTION 16: OTHER INFORMATION

The following sections contain revisions or new statements: 1-16.

References: Existing Safety Data Sheet (SDS).

This Safety Data Sheet was prepared in accordance with EC Regulation (EC) 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830.

LEGEND

LTEL	Long Term Exposure Limit
STEL	Short Term Exposure Limit
DNEL	Derived No Effect Level
PNEC	Predicted No Effect Concentration
PBT	PBT: Persistent, Bioaccumulative and Toxic
vPvB	vPvT: very Persistent and very Toxic
OECD	Organisation for Economic Cooperation and Development

Training advice: Consideration should be given to the work procedures involved and the potential extent of exposure as they may determine whether a higher level of protection is required.

Disclaimers

Customers are urged to ensure that the product is entirely suitable for their own purpose. It is the customers' responsibility to ensure that a suitable and sufficient assessment of the risks created by the use of the product is undertaken. The use of the reagent and the interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of the country where the reagent is in use.

Information contained in this publication or as otherwise supplied to Users is believed to be accurate and is given in good faith, but it is for the Users to satisfy themselves of the suitability of the product for their own particular purpose. Lorne Laboratories Ltd gives no warranty as to the fitness of the product for any particular purpose and any implied warranty or condition (statutory or otherwise) is excluded except to the extent that exclusion is prevented by law. Lorne Laboratories Ltd accepts no liability for loss or damage (other than that arising from death or personal injury caused by defective product, if proved), resulting from reliance on this information. Freedom under Patents, Copyright and Designs cannot be assumed.

Annex to the extended Safety Data Sheet (eSDS)

Not applicable

Date of First Issue
28 August 2001