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Location: Moldova
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Rapid Labs

STATEMENT

We, **Rapid Labs Limited** having a registered office at Unit 2 & 2A, Hall Farm Business Centre, Church Road, Little Bentley, Colchester, Essex CO7 8SD, United Kingdom assign SRL Sanmedico, having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as authorized representative in Republic of Moldova.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Date: March 5th, 2025

Signature: Tracy Wu Rapid Labs Rapid Labs Limited

Unit 2 & 2A, Hall Farm Business Centre,
Church Road, Little Bentley, Colchester,
Essex CO7 8SD, United Kingdom

Certificate of Registration

This certificate has been awarded to

Rapid Labs Limited

Unit 2 & 2A Hall Farm, Business Centre, Church Road, Little Bentley, Colchester, Essex, CO7 8SD, United Kingdom

in recognition of the organization's Quality Management System which complies with

ISO 13485:2016

The scope of activities covered by this certificate is defined below

Please refer to the Appendix

Certificate Number **55321/A/0001/UK/En**

A certificate number of 0001, confirms the Client has a single site Certified & the site is their Head Office or Main site in relation to the Certified scope with URS. A certificate number of 0002, or greater (e.g.: xxxx/B/0002/UK/En) refers to a client that has more than one site certified with URS, as such, the following statement shall apply - 'The validity of this certificate depends on the validity of the main certificate'.

Date of Issue of Certification Cycle	Issue Number	Certificate Expiry Date	Certification Cycle
16 October 2024	**10**	**15 October 2027**	**5**
Revision Date	Revision Number	Original Certificate Issue Date	Scheme Number
11 July 2024	**0**	**09 November 2012**	**n/a**

For detailed explanation for the data fields above, refer to http://www.urs-holdings.com/logos-and-regulations

Issued by Mukesh Singhal - On behalf of the Schemes Manager

Appendix to Certificate

Design, Development, Manufacture and Supply of In-Vitro Diagnostic Products for the Blood Grouping products, Detection of Hormones, Drug of Abuse, Infectious Disease, Tumour Markers and Cardiac Markers, and the related POCT Analyzer. Supply of Glass Vials and Bottles

Certificate Number **55321/A/0001/UK/En**

A certificate number of 0001, confirms the Client has a single site Certified & the site is their Head Office or Main site in relation to the Certified scope with URS. A certificate number of 0002, or greater (e.g.: xxxx/B/0002/UK/En) refers to a client that has more than one site certified with URS, as such, the following statement shall apply - 'The validity of this certificate depends on the validity of the main certificate'.

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For detailed explanation for the data fields above, refer to http://www.urs-holdings.com/logos-and-regulations

Issued by

Mukesh Singhal - On behalf of the Schemes Manager

Declaration of Conformity

for the Fluorescence Immunoassay Analyzer

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices

The undersigned, under their sole responsibility, declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Fluorescence Immunoassay Analyzer
Legal Manufacturer: (Name on Label)	Rapid Labs Ltd. Unit 2 & 2a Hall Farm, Church road, Little Bentley, Colchester, Essex, CO7 8SD United Kingdom
SRN:	GB-MF-000026335
Basic UDI-DI:	5060599400002PNT
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	For quantitative or qualitative detection of human samples with specific in vitro diagnostic test units including Inflammation Markers, Tumor Markers, Nephrology, Diabetes, Cardiac Markers, Coagulation, Endocrinology, Autoimmunity, Infectious Diseases and etc.
IVDR Classification:	Class A [Rule 5(b)]
Notified Body:	Not applicable
CE Certificate:	Not applicable
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
IVDR Assessment Route:	Issuing of the Declaration of Conformity in accordance with Article 17 after drawing up the technical documentation in Annexes II and III of the EU IVDR 2017/746.

Name Rowland King **Position** Managing Director

Signed **Date** 16/05/2022 **Place** Essex

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
2017/746	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices
EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019+A11:2021	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer
EN ISO 18113-1:2011	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general require-ments

Appendix II – Product Listing/Schedule

Catalogue Number / UDI-DI	Device Description	EMDN Code
RL-AFR-100/RL-AFR-100S	Fluorescence Immunoassay Analyzer	W0201020201
RL-AFR-200/RL-AFR-200S		
RL-AFR-300/RL-AFR-301		

Version History

Version	Compiled by	Date	Description
1.0	Emily Swager	16/05/2022	First issue.

Declaration of Conformity

for the Fluorescence Immunoassay

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices

The undersigned, under their sole responsibility, declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Rapid Strips & devices
Legal Manufacturer: (Name on Label)	**Rapid Labs Limited** Unit 2 & 2A Hall Farm, Business Centre, Church road, Little Bentley, Colchester, Essex, CO7 8SD United Kingdom
SRN:	GB-MF-000026335
Basic UDI-DI:	N/A
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	Professional use
IVDR Classification:	As per Appendix II (This document) – Product Listing/Schedule
Notified Body:	N/A
CE Certificate:	N/A
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
IVDR Assessment Route:	*Provide indication of conformity assessment route chosen in accordance with Article 48 of the IVDR.* *For Class A: Issuing of the Declaration of Conformity in accordance with Article 17 after drawing up the technical documentation in Annexes II and III of the EU IVDR 2017/746.* *If Class A provided sterile, must also apply the procedures laid out in Annex IX or Annex XI.*

Name Yanli Wu **Position** Company Director

Signed Yanli Wu **Date** 22/10/2024 **Place** Colchester, UK

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

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EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer
EN ISO 18113-1:2011	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general require-ments

Appendix II –Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code	Class	Rule
D-FICEAD20	CEA Test Device -S/P	54616	B	6
D-FIAFPD20	AFP Test Device -S/P	54060	B	6
D-FIDIMERD10	D-Dimer Test Device -WB/P	61389	C	3k
D-FICKMBD10	CK-MB Test Device -WB/S/P	61385	C	3j
D-FIMYOD25	Myoglobin Rapid Test Device —WB/S/P	61390	B	6
D-FIFABD10	H-FABP Test Device -WB/S/P	53365	B	6
D-FINTPD10	NT-proBNP Test Device -WB/S/P	47352	B	6
D-FITIMCKD20	Troponin I/Myoglobin/CK-MB (3 in 1) Test Device -WB/S/P	47384	B	6
D-FITTMCKD20	Troponin T/Myoglobin/CK-MB (3 in 1) Test Device -WB/S/P	47384	B	6
D-FILHD20	LH Test Device -WB/S/P	65959	B	6
D-FISTRAS20	Strep A Test Device -Swab	63770	B	6
D-FIIABD20	Influenza A+B Test Device -Swab	49117	B	6
D-FIDGMD20	Dengue IgG/IgM Test Device -WB/S/P	48915	C	3b
D-FIDAGD25	Dengue NS1 Test Device -WB/S/P	48915	C	3b
D-FIRSVD20	RSV Test Device -Swab	62587	B	6
D-FISPD10	Streptococcus pneumoniae Test Device -urine	63796	B	6
D-FILPD25	Legionella pneumophila Test Device -urine	63781	B	6
D-FITPSPD40	Syphilis Test Device -WB/S/P	51814	C	3a
D-FIAMHD10	AMH Test Device -WB/S/P	58410	B	6

D-FIFSHD20	FSH Test Device -WB/S/P	54188	B	6
D-FIRFSPD20	Rheumatoid Factor Rapid Test device-S / P	55109	B	6
D-FICRPD25	CRP Test Device-WB/S/P	58768	B	6
D-FIPCTD25	PCT Test Device-WB/S/P	54313	B	6
D-FIFOBD25	FOB Test Device-Feces	66044	B	6
D-FIT4D25	T4 Test Device-S/P	63072	B	6
D-FIHCGD25	β-HCG Test Device-S/P	58789	B	6
D-FITSHD25	TSH Test Device-S/P	54384	B	6
D-FITESD25	Testosterone Test Device-S/P	54184	B	6
D-FIP4D25	Progesterone(P4) Test Device-S/P	54327	B	6
D-FICYSCD25	CysC Test Device-WB/S/P	48177	C	3j
D-FI2MGD25	β2MG Test Device-WB/S/P	53930	B	6
D-FINGALD25	N-GAL Test Device-Urine	47426	B	6
D-FIHBA1CD25	HbA1c Test Device-WB	65958	B	6
D-FIIGED25	IgE Test Device-WB/S/P	60380	B	6
D-FIFED25	Ferritin Rapid test Device -WB/S/P	58769	B	6
D-FICOVID10	COVID-19 Antigen Rapid Test Device – Nasopharyngeal Swab	64787	B	6
D-FIPRLD10	PRL (Prolactin)Test device (Whole Blood/Serum/Plasma)	58765	B	6
D-FIPRLD25	PRL (Prolactin)Test device (Whole Blood/Serum/Plasma)	58765	B	6
D-FIT3D25	T3 Test Device-S/P 25T	63082	B	6
D-FIT3WBD10	T3 Test Device WB/S/P	63082	B	6
D-FIT3WBD25	T3 Test Device WB/S/P	63082	B	6
D-FIVDC25	Vitamin D Test Device (Serum/Plasma)	65347	B	6
D-FIVDC10	Vitamin D Test Device (Serum/Plasma)	65347	B	6
D-FIVDWBD25	Vitamin D Rapid Test Device WB/S/P	65347	B	6
D-FIVDWBD10	Vitamin D Rapid Test Device WB/S/P	65347	B	6
D-FITROPD25	cTnI Test Device(WB/S/P)	54010	C	3j
D-FITROPD10	cTnI Test Device(WB/S/P)	54010	C	3j
D-FIPNEUD20	Mycoplasma pneumoniae Antigen Test Device - Throat Swab	51213	B	6
D-FIHCGWBD25	β-HCG Test Device-WholeBlood/Serum/Plasma	63072	B	6
D-FIPSAD10	PSA Test Device -Serum/Plasma	54670	C	3h
D-FIPSAWBD10	PSA Test Device -Whole Blood/Serum/Plasma	54670	C	3h
D-FIPSAWBD25	PSA Test Device -Whole Blood/Serum/Plasma	54670	C	3h
D-FIT4WBD10	T4 Test Device-WB/S/P	63072	B	6
D-FIT4WBD25	T4 Test Device-WB/S/P	63072	B	6
D-FITSHWBD10	TSH Test Device-WB/S/P	54384	B	6
D-FITSHWBD25	TSH Test Device-WB/S/P	54384	B	6
D-FIFT3WBD10	FT3 Test Device -WB/S/P	54419	B	6
D-FIFT3WBD25	FT3 Test Device -WB/S/P	54419	B	6
D-FIFT4WBD10	FT4 Test Device -WB/S/P	63071	B	6
D-FIFT4WBD25	FT4 Test Device -WB/S/P	63071	B	6

D-FIIGAWBD10	IgA Test Device -WB/S/P	0	B	6
D-FIIGAWBD25	IgA Test Device -WB/S/P	0	B	6
D-FIhsCTIK10	High-Sensitivity Cardiac Troponin T Test Device-WB/S/P	54004	C	3j
D-FIhsCTIK25	High-Sensitivity Cardiac Troponin T Test Device-WB/S/P	54004	C	3j
D-FICTNTD10	Cardiac Troponin T Test Device-WB/S/P	54004	C	3j
D-FICTNTD25	Cardiac Troponin T Test Device-WB/S/P	54004	C	3j

Version History

Version	Compiled by	Date	Description
1.0	Yanli Wu	22/10/2024	Initial Issue

Rapid Labs Ltd
Unit 2 Hall Farm
Church Road
Little Bentley, Colchester
Essex. CO7 8SD. U.K.

Rapid Labs®

Certificate of Qualified Engineer

In view of the excellent performance of **Pohilco Irina** from **Sanmedico SRL** Company , in Fluorescence Immunoassay Analyzer((RL-AFR-301) training and professional performance and ability accumulation in related fields, we hereby solemnly declare that **Pohilco Irina** has the ability to install, troubleshoot and handle the maintenance of the Fluorescence Immunoassay Analyzer (RL-AFR-301) .Identified as a qualified engineer of the instrument.

This certificate is effective as of the date of issuance and is valid for 10 years. During the validity period, **Pohilco Irina** can install the instrument, training and maintenance and other related work.

Rapid Labs Limited

Director: Tracy Wu

Signature: Tracy Wu

Rapid Labs Limited

Date: 25, April, 2025