Lloyd's Register
LRQA

EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM

In accordance with the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

Mast Group Limited
Mast House, Derby Road,
Bootle, Merseyside
United Kingdom

has been assessed against the requirements of Annex IV of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached certificate schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Certificate No:	LRQ 0932114/C
Original Approval:	25 May 2004
Current Certificate:	1 June 2018
Certificate Expiry:	31 May 2021

LRQA Notified Body Number 0088

Digitally signed by Monastîrschii Viorica
Date: 2020.12.07 12:42:01 EET
Reason: MoldSign Signature
Location: Moldova

Issued by: Lloyd's Register Quality Assurance Limited

1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom.

IVD solutions through partnership

Mast Group

Mast Group Ltd.
Mast House
Derby Road
Bootle
Merseyside L20 1EA
United Kingdom

Tel. +44 (0)151 933 7277
Fax +44 (0)151 944 1332

www.mastgrp.com

EC DECLARATION OF CONFORMITY

We hereby declare that the devices described below comply with those provisions which apply to them of the European Directive 98/79/EC on *in vitro* diagnostic medical devices, as set out in UK Statutory Instrument 2002 No. 618 "The Medical Device Regulations."

This declaration is valid for the IVD medical devices described below which are placed on the market by ourselves on or after the date hereof and which bear the CE mark. It is also valid for all the IVD medical devices described below which are manufactured by us and placed on the market on or after the date hereof by third parties with our consent and which bear the CE mark. All supporting documents relating to this declaration are retained at the manufacturer's premises.

Product code	Product description	IVD Directive classification	EDMS code
Various	**MAST® ID identification test paper products** - discs, rings and strips. Products for presumptive identification of biochemical reactions or detection of a specific reaction profiles in microbes.	Self certification Annex III excluding section 6	1402020100, 1402020200, 1402020400, 1402020800, 1402029000. (codes registered - 24/03/2003)

Standards applied: EN ISO 13485:2016, ISO 9001:2015, EN ISO 14971:2012, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 15223-1:2016, EN ISO 15223-2:2010.

Declaration made by .....

Date: 30 January 2019

D N Hogben, Quality Assurance and Regulatory Affairs Manager – Mast Group Ltd.

Document valid till: 31 December 2021

Lloyd's Register

Certificate of Approval

This is to certify that the Management System of:

Mast Group Ltd

Mast House, Derby Road, Bootle, L20 1EA, United Kingdom

has been approved by LRQA to the following standards:

ISO 9001:2015

David Derrick - Area Operations Manager UK & Ireland

Issued By: Lloyd's Register Quality Assurance Limited

Current Issue Date: 7 June 2018
Expiry Date: 31 May 2021
Certificate Identity Number: 10090586
Certificate Approval Number: LRQ 0932114/A

Original Approvals:
ISO 9001 – 14 June 1994

Approval Number(s): ISO 9001 – 0003467

The scope of this approval is applicable to:
Design, manufacture and supply of in-vitro diagnostic devices and associated services.

REPUBLICA MOLDOVA, mun. CHISINAU
S.R.L.
"SANMEDICO"
IDNO 1003
SOCIETATEA CU RĂ

UKAS
MANAGEMENT
SYSTEMS
001

Lloyd's Register

Certificate of Approval

This is to certify that the Management System of:

Mast Group Ltd

Mast House, Derby Road, Bootle, L20 1EA, United Kingdom

has been approved by LRQA to the following standards:

ISO 13485:2016

David Derrick - Area Operations Manager UK & Ireland

Issued By: Lloyd's Register Quality Assurance Limited

Current Issue Date: 7 June 2018
Expiry Date: 31 May 2021
Certificate Identity Number: 10090587
Certificate Approval Number: LRQ0932114/E

Original Approvals:
ISO 13485 14 June 1994

Product Approval Number: ISO 13485 – 0003466

The scope of this approval is applicable to:
Design, manufacture and supply of in-vitro diagnostic devices and associated services.

REPUBLICA MOLDOVA, mun. CHISINAU
S.R.L.
"SANMEDICO"
SOCIETATEA CU RASPUNDERE LIMITATA

UKAS
MANAGEMENT
SYSTEMS
001

Declaration Ref No: DC11-0051

Atlas Medical

CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

We,

Atlas Medical

Head office: Ludwig-Erhard-Ring 3
D-15827 Blankenfelde-Mahlow
Tel: +49 - 33708 – 3550 30
Email: info@atlas-medical.com

Middle East Site: Sahab Free Zone Area, P. O. Box 212555, Amman, Jordan.
Tel.: +962 6 4026468
Fax: +962 6 4022588
Email: info@atlas-medical.com

Declare our responsibility that the following product:

See Attached list

- Comply with all essential requirements (AnnexI) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
- This product is produced under Atlas quality system (ISO13485:2016) issued by Lloyd's Register Quality Assurance.
- Comply with the essential requirements of following standards (EN 18113-1, -2,-4:2011, EN ISO 15223:2016 , EN ISO 23640:2015, EN ISO 14971:2012, ISO 2859/1:1999, EN ISO 13612:2002, EN ISO 13641:2002.

And

Intended for In-Vitro Professional use only.

"SANMEDICO"

Manufacturer
Atlas Medical
Ludwig-Erhard-Ring 3
D-15827 Blankenfelde-Mahlow

Atlas Medical	Issue date	Date of review	Management approval	MRXDO10F.10 08.02.2011
	December.2011	26.11.2019		

Atlas Medical

CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

RPR Carbon Antigen (Coarse Grain) Kit, 1000 Tests.
CRP Latex Kit, 100 Tests (4ml Latex, 2x1.0ml Controls).
RPR Syphilis (Coarse Grain) Kit, 500 Tests (10 ml latex, 2x1ml control).
RPR Carbon Antigen Kit, 100 Tests
D-Dimer Latex Kit, 100 Tests
Streptococcus Latex Kit, 6 Groups, 6x50 Tests (6x2ml Latex, 1.0ml Positive Control, 2x10ml Extraction Enzyme. Glass Slide).
Drabkins Reagent, 40x, 6x50ml (3000 Tests).
Drabkins Reagent, 40x, 50ml/vial (500 Tests).
RF Latex Kit, 100 Tests (4ml Latex, 2x1.0ml controls).
ASO Latex Kit, 100 Tests (4ml Latex, 2x1.0ml controls).
VDRL Antigen Kit,(5 ml+ 55 ml buffer+3 ml positive control + 3 ml negative control)
TPHA Kit, 100 Tests
Staphylococcus Latex Kit, 100 Tests (4ml Test Latex, 2ml Control Latex, Glass Slide).

REPUBLICA MOLDOVA S.R.L. "SANMEDICO"

Atlas Medical Quality Diagnostic Products

GMED
GROUPE LNE

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 36655 rev.0

GMED certifie que le système de management de la qualité développé par

GMED certifies that the quality management system developed by

ATLAS MEDICAL GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow GERMANY

pour les activités
for the activities

Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic in vitro .

Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices.

réalisées sur le(s) site(s) de
performed on the location(s) of

Voir addendum

See addendum

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

ISO 13485: 2016

Début de validité */ Effective date* **March 23rd, 2020 (included)**
Valable jusqu'au */ Expiry date :* **October 8th, 2020 (included)**
Etabli le */ Issued on :* **March 23rd, 2020**

GMED SAS GMED SAS
GMED GROUPE LNE
DocuSigned by:
Béatrice LYS
BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

cofrac
CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0608
Liste des sites accrédités et portée disponible sur www.cofrac.fr

GMED N° 36655–0
Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

GMED_SQ_plus3sites-F-V0-07-2018

GMED
GROUPE LNE

Addendum au certificat n° 36655 rev. 0 page 1/1
Addendum of the certificate n° 36655 rev. 0
Dossier / *File* N°P172375

Ce certificat couvre les activités et les sites suivants :
This certificate covers the following activities and sites:

French version :
Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic *in vitro* à usage professionnel et/ ou d'autodiagnostic, dans les domaines du groupage sanguin, de la microbiologie, de la biochimie, de la toxicologie, de l'oncologie, de la cardiologie, de l'histologie, de l'endocrinologie et des maladies infectieuses, dans les techniques d'Agglutination/ ELISA/ Tests rapides/ Colorimétrie/ Disques antibiotiques.

English version:
Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices for professional use and/or for self-testing, in the field of Immunohematology, Microbiology, Biochemistry, Toxicology, Oncology, Cardiology, Histology, Endocrinology Biosensors and Infectious diseases, in techniques of Agglutination/ ELISA/ Rapid tests/ Colorimetry/Antibiotic disks.

ATLAS MEDICAL GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow
GERMANY

French version:
Siège social, responsable de la mise sur le marché
English version:
Headquarter, legal manufacturer

****

Sahab Industrial Zone Area
King Abdullah II Industrial City
Amman 11512
JORDAN

French version:
Conception, fabrication et contrôle final
English version:
Design, manufacture and final control

****

William James House
Cowley Road,
Cambridge, CB OWX
United Kingdom

French version:
Contact réglementaire
English version:
Regulatory Administration

****

3 sites / 3 *sites*

S.R.L. "SANMEDICO"

GMED

DocuSigned by:
Béatrice LYS
EF35B0B3BA0A4A5...

On behalf of the President
Béatrice LYS
Technical Director

Atlas Medical

Declaration Ref No: DC11-0028

CE Declaration of Conformity

We,
Atlas Medical

Head office: William James House, Cowley Road, Cambridge, CB4 0WX, UK
Tel: +44 1223 858 910
Fax: +44 1223 858 524
Email: info@atlas-site.co.uk

Middle East Site: Sahab Free Zone Area, P. O. Box 212555, Amman, Jordan.
Tel.: +962 6 4026468
Fax: +962 6 4022588
Email: info@atlas-medical.com

Declare our responsibility that the following product:

Streptococcus Latex Kit

Is produced under Atlas quality system (ISO9001: 2008) and (ISO13485: 2003) supported by Lloyd's certificate and complies with the essential requirements of

In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex I
And
EN 18113-1, -2 :2011, EN ISO 15223:2012
EN ISO 14971:2012, EN ISO 13640:2002, ISO 2859/1:1999,
EN ISO 13612:2002, EN ISO 13641:2002

And
Intended for In-Vitro Professional use only.

This Declaration includes the batches produced beyond this day according to the product Lot Log.

Manufacturer
Atlas Medical
William James House, Cowley Rd.
Cambridge, CB4 0WX, UK

Atlas Medical
Quality Diagnostic Products

DECLARATION OF CONFORMITY

1) **Manufacturer** *(Name, department)*: **CJSC EKOlab**

Address: 1 Budennogo Str., Elektrogorsk, Moscow region, 142530, Russia

2) **European authorized representative: CEpartner4U BV,**

Address: **ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS**;
(on product labels printed as:
CEpartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS. www.cepartner4u.com)

3) **Product(s)** *(name, type or model/batch number, etc.)*:

- Rabbit plasma

4) **The product(s) described above is in conformity with:**

Title	Document No.
In vitro Diagnostic Medical Devices Directive	98/79/EC

5) **Additional information** *(conformity procedure, Notified Body, CE certificate, etc.)*:

Conformity assessment procedure for CE marking: *In vitro* Diagnostic Medical Device Directive, Annex III

Registration nr. : pending

Elektrogorsk, Russia; 2017-11-03

(Place & date of issue (yyyy-mm-dd))

V.Y. Borisov, General Director, CJSC EKOlab

(name, function and signature of manufacturer)

S.R.L. "SANMEDICO"

Declaration form: Standard ISO/IEC 17050-1:2010

Appendix

Date: 2017-11-08

List of devices.

Device name	Type/ model/ref number	Risk class / rule[1]	Code: EMDS/GMDN	First date of CE-compliance
Rabbit plasma		Low risk	15011290/0	2017-11-08

S.R.L. "SANMEDICO"

[1] See EDMS codes: http://www.edma-ivd.be/ (products classification)/Preference GMDN code

CEpartner4U

Certificate number: 2017-IVD/193

Certificate of CE-Notification

This is to certify that, in accordance with the *In Vitro* Diagnostic Medical Device Directive 98/79/EC, **CEpartner4U BV** agrees to perform all duties and responsibilities as the Authorized Representative for

CJSC EKOlab

1 Budennogo Str., Elektrogorsk, Moscow region, 142530, Russia

as stipulated and demanded by the aforementioned Directive. The Dutch Competent Authorities have accepted the manufacturer's medical device registrations by CEpartner4U as listed on the product list attached to the manufacturer's Declaration of Conformity:

Device group: Rabbit plasma

IVD devices were registered under number:

Registration number Rabbit plasma: NL-CA002-2017-43242

with Dutch Competent Authorities as a consequently this IVD devices were entered in EUDAMED by Dutch Competent Authorities

The manufacturer has provided CEpartner4U with all necessary documentation, together with an appropriate Declaration of Conformity that the IVD medical devices fulfil the essential requirements of Directive 98/79/EC.

2017-12-18

Olga Teirlinck
Consultant CEpartner4U BV

REPUBLICA MOLDOVA, mun. CHIŞINĂU S.R.L. "SANMEDICO" IDNO 1003602008154 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

CEpartner4U
Esdoornlaan13
3951 DB Maarn NL
tel: +31 (0)343 442 524
www.cepartner4u.nl

Certificat

Certificate

N° 2007/28642.5

AFNOR Certification certifies that the management system implemented by:
AFNOR Certification удостоверяет, что система менеджмента организации:

ZAO "EKOlab"
ЗАО «ЭКОлаб»

for the following activities:
для следующих областей деятельности:

DEVELOPMENT, PRODUCTION, STORAGE AND SALE OF MEDICAL DEVICES FOR IN-VITRO DIAGNOSTICS.

РАЗРАБОТКА, ПРОИЗВОДСТВО, ХРАНЕНИЕ И РЕАЛИЗАЦИЯ МЕДИЦИНСКИХ ИЗДЕЛИЙ ДЛЯ IN-VITRO ДИАГНОСТИКИ.

has been assessed and found to meet the requirements of:
проверена и признана соответствующей требованиям стандарта:

ISO 13485:2016

and is developed on the following locations:
и действует на следующих площадках:

142530, RUSSIA, MOSCOW REGION, ELEKTROGORSK CITY, Budennogo str., 1-1A
142530, РОССИЯ, МОСКОВСКАЯ ОБЛАСТЬ, г. ЭЛЕКТРОГОРСК, ул. Буденного, 1-1A

This certificate is valid from (year/month/day) **2019-06-28** until **2022-06-27**
Данный сертификат действителен с (год/ месяц/ день) *до*

Ce document est signé électroniquement. Il constitue un original électronique à valeur probatoire
This document is electronically signed. It stands for an electronic original with probationary value

Franck LEBEUGLE
Managing Director of AFNOR Certification
Генеральный директор AFNOR Certification

Scan this QR code to check the validity of the certificate.
Чтобы проверить действительность данного сертификата, отсканируйте этот QR код