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)

Digitally signed by Gangan Dumitru
Date: 2019.11.22 11:22:07 EET
Reason: MoldSign Signature
Location: Moldova

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

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

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

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SAS au capital de 18 187 000 € - 479 076 002 RCS Bobigny - www.afnor.org

REPUBLICA MOLDOVA, mun. CHISINĂU
PENTRU CONTRACTE ȘI FACTURI
"SANMEDICO"
IDNO 1003602006
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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

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

REPUBLICA MOLDOVA, MUN. CHIȘINĂU
PENTRU CONTRACTE ȘI FACTURI
"SANMEDICO"
IDNO 1003602008
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate
Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 17 08 80997 017

Model(s): For Detail Models see attachment

Facility(ies):
ACON Laboratories, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

AZURE Institute, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate
Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 17 08 80997 017

Manufacturer: ACON Laboratories, Inc.
10125 Mesa Rim Road
San Diego CA 92121
USA

EC-Representative: Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover
GERMANY

Product Category(ies): In Vitro diagnostics for the detection of human infections and tumor markers, blood glucose measuring self-testing systems, self-testing devices for clinical chemistry, hematology and pregnancy

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. See also notes overleaf.

Report No.: SH17743EXT01

Valid from: 2017-09-13
Valid until: 2022-09-12

Date, 2017-08-30

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

"SANMEDICO" S.R.L.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Attachment for Certificate No V1 17 08 80997 017

Supplement 001 dated 2017-08-30

Product Service

Total PSA EIA Test Kit,
PT Coagulation Monitoring System (CCM-121),
PT Coagulation Test Strips (CCS-121),
Cholesterol Monitoring System (CCM-111),
CHOL Total Cholesterol Test Devices (CCS-111),
TRIG Triglycerides Test Devices (CCS-112),
HDL High Density Lipoprotein Test Devices (CCS-113),
3-1 Lipid Panel Test Devices (CCS-114),
Cholesterol CTRL Control Devices,
Cholesterol Monitoring System (CCM-101),
CHOL Total Cholesterol Test Strips (CCS-101),
PT/INR Monitoring System (CCM-151),
PT/INR Test Strips (CCS-151),
Hemoglobin Testing System (CCM-141),
Hemoglobin Test Strips (CCS-141),
hCG Pregnancy Rapid Test Cassette (Urine),
Pregnancy Rapid Test Midstream

Munich, MHS-CRT, 2017-08-30

I. Preiß

Stefan Preiß

Certification Medical Technology

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Attachment for Certificate No V1 17 08 80997 017

Supplement 001 dated 2017-08-30

Product Service

For the product(s)/product category (ies):

On Call Plus Blood Glucose Monitoring System,
On Call Plus Blood Glucose Test Strips,
On Call EZ II Blood Glucose Monitoring System,
On Call Redi Blood Glucose Monitoring System,
On Call Redi II Blood Glucose Test Strips,
On Call Advanced Blood Glucose Monitoring System,
On Call Advanced Blood Glucose Test Strips,
On Call Platinum Blood Glucose Monitoring System,
On Call Platinum Blood Glucose Test Strips,
On Call Chosen Blood Glucose Monitoring System,
On Call Chosen Blood Glucose Test Strips,
On Call Vivid Blood Glucose Monitoring System (OGM-101),
On Call Vivid Blood Glucose Test Strips (OGS-101),
On Call Vivid Pal Blood Glucose Monitoring System (OGM-102),
On Call Sharp Blood Glucose Monitoring System (OGM-121),
On Call Sharp Blood Glucose Test Strips (OGS-121)
On Call Plus II Blood Glucose Monitoring System (OGM-171),
On Call Plus II Blood Glucose Test Strips (OGS-171),
On Call Extra Blood Glucose Monitoring System (OGM-191),
On Call Extra Blood Glucose Test Strips (OGS-191),
On Call GK Dual Blood Glucose & Ketone Monitoring System (OGM-161),
On Call Blood Ketone Test Strips (OGS-161),
D-ONE Blood Glucose Monitoring System,
D-ONE Blood Glucose Test Strips,
Urinalysis Reagent Strips (Urine),
UTI Urinary Tract Infection Test Strips,
Toxoplasma IgG EIA Test Kit,
Toxoplasma IgM EIA Test Kit,
Rubella IgG EIA Test Kit,
Rubella IgM EIA Test Kit,
CMV IgG EIA Test Kit,
CMV IgM EIA Test Kit,

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A1 / 04.11

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

DNV·GL

Certificate No: 282710-2019-AQ-MCW-FINAS
Place and date: Moscow, 14 February 2019

Appendix to Certificate

XEMA Co, LTD
Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
XEMA Co, LTD	bldg. 48, 9-th Parkovaya str., Moscow, Russian Federation, 105264	Design and development, manufacturing and sales of in vitro tests for food and feed control, clinical and veterinary diagnostics and forensic investigations.
XEMA Co, LTD (Production site)	Trubetskaya str., 2B, Balashikha, Moscow region, Russian Federation, 125000	Design and development, manufacturing and sales of in vitro tests for food and feed control, clinical and veterinary diagnostics and forensic investigations.

DNV·GL

MANAGEMENT SYSTEM CERTIFICATE

Certificate No:
282710-2019-AQ-MCW-FINAS

Initial certification date:
14 February 2019

Valid:
14 February 2019 - 14 February 2022

This is to certify that the management system of

XEMA Co, LTD

bldg. 48, 9-th Parkovaya str., Moscow, Russian Federation, 105264
and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:
ISO 9001:2015

This certificate is valid for the following scope:
Design and development, manufacturing and sales of in vitro tests for food and feed control, clinical and veterinary diagnostics and forensic investigations.

Place and date:
Moscow, 14 February 2019

FINAS
Finnish Accreditation Service
S001 (EN ISO/IEC 17021)

For the issuing office:
DNV GL – Business Assurance
Trekhprudny per. 9 build. 2, office 406,
Moscow, Russian Federation

S. Groubine

Serguei Groubine
Management Representative

Polmed.de
Vertretung und Repräsentanz

Annex to the Certificate No.:
Anhang zum Zertifikat Nr.:

AR/IVMD/Xema/12-2016

The following medical devices can be placed on the market in the Federal Republic of Germany, in the member states of the European Economic Community (EEC) and in the other contract states of the agreement about the European Economic Area.

Die folgenden Medizinprodukte in der Bundesrepublik Deutschland, in den Mitgliedsstaaten der Europäischen Wirtschaftsgemeinschaft (EG) und in den Vertragsstaaten der EG in den Verkehr gebracht werden dürfen.

	Nomenclature term Nomenklaturbezeichnung	Catalog number Katalognummer	Name of device Produktbezeichnung	DIMDI Product registration number Registriernummer
1.	THYROID PEROXIDASE (INCL. MICROSOMAL) ANTIBODIES	K131	aTPO EIA Cat. Nr K131	DE/CA37/IVD/13/44
2.	THYROGLOBULIN AUTOANTIBODIES	K132	aTG EIA Cat. Nr K132	DE/CA37/IVD/13/43
3.	MPO ANCA	K133	aMPO EIA Cat. Nr K133	DE/CA37/IVD/13/42
4.	TISSUE TRANSGLUTAMINASE ANTIBODIES	K160 K161	Anti-tTG IgG EIA Cat. Nr K160; Anti-tTG IgA EIA Cat. Nr K161	DE/CA37/IVD/13/41
5.	GLIADIN ANTIBODIES	K180 K181 K182A K182G	Gliadin IgG EIA Cat. Nr K180; Gliadin IgA EIA Cat. Nr K181 ; Deamidated Gliadin IgA EIA, Deamidated Gliadin IgG EIA	DE/CA37/IVD/13/40
6.	IMMUNOGLOBULIN E – TOTAL	K200	Total IgE EIA Cat. Nr K200	DE/CA37/IVD/13/39
7.	THYROID STIMULATING HORMONE	K201 K201A	TSH EIA Cat. Nr K201; TSH Plus EIA Cat. Nr K201A	DE/CA37/IVD/13/38
8.	LUTEINISING HORMONE	K202	LH EIA Cat. Nr K202	DE/CA37/IVD/13/37
9.	FOLLICLE STIMULATING HORMONE	K203	FSH EIA Cat. Nr K203	DE/CA37/IVD/13/36
10.	HUMAN GROWTH HORMONE	K204	GH EIA Cat. Nr K204	DE/CA37/IVD/13/35
11.	HUMAN CHORIONIC GONADOTROPIN TOTAL	K205	HCG EIA Cat. Nr K205	DE/CA37/IVD/13/34
12.	PROLACTIN	K206	Prolactin EIA Cat. Nr K206	DE/CA37/IVD/13/33
13.	PROGESTERONE	K207 K207S	Progesterone EIA Cat. Nr K207 ; Salivary Progesterone EIA	DE/CA37/IVD/13/32
14.	ESTRADIOL	K208	Estradiol EIA Cat. Nr K208	DE/CA37/IVD/13/31
15.	TESTOSTERONE (WITH DEHYDRO AND FREE TESTOSTERONE)	K209 K209S	Testosterone EIA Cat. Nr K209 ; Salivary Testosterone EIA	DE/CA37/IVD/13/30
16.	CORTISOL	K210 K210S	Cortisol EIA Cat. Nr K210 ; Salivary Cortisol EIA	DE/CA37/IVD/13/29
17.	TRIIODOTHYRONINE	K211	T3 EIA Cat. Nr K211	DE/CA37/IVD/13/28
18.	THYROXINE	K212	T4 EIA Cat. Nr K212	DE/CA37/IVD/13/27
19.	FREE TRIIODOTHYRONINE	K213	Free T3 EIA Cat. Nr K213	DE/CA37/IVD/13/26
20.	FREE THYROXINE	K214	Free T4 EIA Cat. Nr K214	DE/CA37/IVD/13/25
21.	DEHYDRO-EPIANDROSTERONE SULPHATE (INCL. DHEA)	K215	DHEA-S EIA Cat. Nr K215	DE/CA37/IVD/13/24
22.	17 OH PROGESTERONE	K217	17-OH-Progesterone EIA Cat. Nr K217	DE/CA37/IVD/13/22
23.	CANCER ANTIGEN 125	K222	CA 125 EIA Cat. Nr K222	DE/CA37/IVD/13/23
24.	CANCER ANTIGEN 19-9	K223	CA 19.9 EIA Cat. Nr K223	DE/CA37/IVD/13/21
25.	CARCINOEMBRYONIC ANTIGEN	K224	CEA EIA Cat. Nr K224	DE/CA37/IVD/13/20

The above-mentioned medical products are marked with the CE symbol.
Die oben genannten medizinischen Produkte sind mit dem CE-Zeichen gekennzeichnet.

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Vertretung und Repräsentanz

Certificate
Of Marketing Authorization of Medical Product

Nr. AR/IVMD/Xema/12-2016

Issued on the basis of the Declaration of conformity and registration taking into account Article 10 of Directive 98/79/EC on In Vitro Diagnostic Medical Devices and Medical Devices Act (MPG) § § 5,25,29,30

Ausgestellt auf Grund der Konformitätserklärung und Registrierung unter Berücksichtigung der Richtlinie 98/97/EG Artikel 10 über In-vitro-Diagnostika und Medizinproduktgesetz (MPG) §§ 5,25,29.30

Manufacturer: Hersteller	**Xema Co., Ltd.** bld.4, 48, The 9th Parkovaya str. Moscow 105264, RUSSIA, info@xema.ru; www.xema.ru
Product name: Produkt	See annex to the Certificate Siehe Anhang zum Zertifikat
Product Classification: Produktklassifizierung	In Vitro Diagnostic Medical Devices In-vitro-Diagnostikum (IVD) Medizinprodukte
Category: Kategorie	Common/ Other IVD Sonstige IVD-Produkte
Conformity Module: Konformitätsmodul	Module A (EC Declaration of Conformity) (Annex III, except point6, Directive 98/79/EC) Modul A (EG-Konformitätserklärung) (Anhang III, außer Nummer 6, Richtlinie 98/79 / EG)
Lead Competent Authority: Zuständige Behörde	DIMDI – German Institute of Medical Documentation and Information DIMDI – Deutsches Institut für Medizinische Dokumentation und Information
Product Registration Ref. No.: (Per Article 10, Directive 98/79/EC) Produkt Registrationsnummer (Gemäß Artikel 10 der Richtlinie 98/79 / EG)	See annex to the Certificate Siehe Anhang zum Zertifikat

Date of issue: 2016-12-31
Das Ausstellungsdatum

Valid to : 2019-12-31
Gültig bis

Represented in the EC by Polmed.de
Steinacker 5, 73773 Aichwald, Germany
email: info@polmed.de
tel: +49 711 52853279

Vertretung und Repräsentanz
Polmed.de
D-73773 Aichwald Steinacker 5

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PENTRU CONTROL ŞI FACTURĂ
"SANMEDICO"
IDNO 1003602008
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Annex to the Certificate No.:
Anhang zum Zertifikat Nr.:

AR/IVMD/Xema/12-2016

The following medical devices can be placed on the market in the Federal Republic of Germany, in the member states of the European Economic Community (EEC) and in the other contract states of the agreement about the European Economic Area.

Die folgenden Medizinprodukte in der Bundesrepublik Deutschland, in den Mitgliedsstaaten der Europäischen Wirtschaftsgemeinschaft (EG) und in den Vertragsstaaten der EG in den Verkehr gebracht werden dürfen.

	Nomenclature term Nomenklaturbezeichnung	Catalog number Katalognummer	Name of device Produktbezeichnung	DIMDI Product registration number Registriernummer
50.	NEURON SPECIFIC ENOLASE	K234	NSE EIA Cat. Nr K234	DE/CA37/IVD/13/52
51.	OTHER OTHER TUMOUR MARKERS	K239	HE – 4 EIA Cat. Nr K239	DE/CA37/IVD/13/53
52.	HSV IgG	K104	HSV ½ IgG EIA (Cat. Nr K104)	DE/CA37/IVD/13/67
53.	HSV IgM	K104M	HSV ½ IgM EIA (Cat. Nr K104M)	DE/CA37/IVD/13/66
54.	MYCOPLASMA ANTIBODY ASSAYS	K106	Mycoplasma IgG EIA (Cat. Nr K106)	DE/CA37/IVD/13/65
55.	SYPHILIS ANTIBODY ASSAYS TOTAL	K111	Treponema pallidum Total Ab EIA (Cat. Nr K111)	DE/CA37/IVD/13/64
56.	SYPHILIS ANTIBODY IGG	K111G	Treponema pallidum IgG EIA (Cat. Nr K111G)	DE/CA37/IVD/13/63
57.	SYPHILIS ANTIBODY IGM	K111M	Treponema pallidum IgM EIA (Cat. Nr K111M)	DE/CA37/IVD/13/62
58.	H. PYLORI ANTIBODY ASSAYS	K119	H.pylori IgG EIA (Cat. Nr K119)	DE/CA37/IVD/13/61
59.	H. PYLORI ANTIBODY ASSAYS	K119M	H.pylori IgM EIA (Cat. Nr K119M)	DE/CA37/IVD/13/60
60.	ASPERGILLUS	K121	Aspergillus IgG EIA (Cat. Nr K121)	DE/CA37/IVD/13/59
61.	OTHER OTHER BACTERIOLOGY IMMUNOASSAY	K126	Ureaplasma IgG EIA (Cat. Nr K126)	DE/CA37/IVD/13/58
62.	GIARDIA LAMBLIA	K171	Giardia lamblia Total Ab EIA (Cat. Nr 171)	DE/CA37/IVD/13/57
63.	OTHER TUMOUR MARKER RAPID TESTS	X22OV	XEMAtestOvaScreen (Cat. Nr X22OV)	DE/CA37/IVD/13/56
64.	OTHER TUMOUR MARKER RAPID TESTS	X222	XEMAtestCA125 (Cat. Nr X222)	DE/CA37/IVD/13/55
65.	OTHER TUMOUR MARKER RAPID TESTS	X239	XEMAtestHE4 (Cat. Nr X239)	DE/CA37/IVD/13/54
66.	IMMUNOGLOBULIN A IgA	K276	SECRETORY IgA (sIgA) EIA (Cat. No. K276)	DE/CA37/IVD/13/68
67.	ECHINOCOCCUS	K175	Cestodes IgG EIA (Cat. No. K175)	DE/CA37/IVD/13/72E
68.	DISTOMATOSIS	K176	Fasciola IgG EIA (Cat. No. K176)	DE/CA37/IVD/13/71E
69.	TESTOSTERONE (WITH DEHYDRO AND FREE TESTOSTERONE)	K219	Free Testosterone EIA (Cat. No. K219)	DE/CA37/IVD/13/70E
70.	HUMAN PLACENTAL LACTOGEN HPL	K246	Human Placental Lactogen EIA (Cat. No. K246)	DE/CA37/IVD/13/69E

The above-mentioned medical products are marked with the CE symbol.
Die oben genannten medizinischen Produkte sind mit dem CE-Zeichen gekennzeichnet.

Represented in the EC by Polmed.de
Steinacker 5, 73773 Aichwald, Germany
email: info@polmed.de
tel: +49 711 52853279

Vertretung und Repräsentanz Polmed.de D-73773 Aichwald Steinacker 5

Date: **December 31, 2016**

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Vertretung und Repräsentanz

Annex to the Certificate No.:
Anhang zum Zertifikat Nr.:

AR/IVMD/Xema/12-2016

The following medical devices can be placed on the market in the Federal Republic of Germany, in the member states of the European Economic Community (EEC) and in the other contract states of the agreement about the European Economic Area.

Die folgenden Medizinprodukte in der Bundesrepublik Deutschland, in den Mitgliedsstaaten der Europäischen Wirtschaftsgemeinschaft (EG) und in den Vertragsstaaten der EG in den Verkehr gebracht werden dürfen.

	Nomenclature term Nomenklaturbezeichnung	Catalog number Katalognummer	Name of device Produktbezeichnung	DIMDI Product registration number Registriernummer
26.	ALPHAFETOPROTEIN	K225	AFP EIA Cat. Nr K225	DE/CA37/IVD/13/19
27.	CANCER ANTIGEN 15-3	K226	M12 (CA 15.3) EIA Cat. NrK226	DE/CA37/IVD/13/18
28.	OTHER CANCER ANTIGENS	K227 K228	MUC1 M22 EIA Cat. Nr K227; MUC1 M20 EIA Cat. Nr K228	DE/CA37/IVD/13/17
29.	OTHER OTHER TUMOUR MARKERS	K232	Thyroglobulin EIA Cat. Nr K232	DE/CA37/IVD/13/16
30.	ß HUMAN CHORIONIC GONADOTROPIN (INCL. SUBUNIT)	K235	Free beta HCG EIA Cat. Nr K235	DE/CA37/IVD/13/15
31.	PREGNANCY ASSOCIATED PLASMA PROTEIN - A (DOWNS)	K238	PAPP-A EIA Cat. Nr K238	DE/CA37/IVD/13/14
32.	OTHER OTHER PLASMA PROTEINS	K240	Alveomucin EIA Cat. Nr K240	DE/CA37/IVD/13/13
33.	C-REACTIVE PROTEIN	K250	CRP EIA Cat. Nr K250	DE/CA37/IVD/13/12
34.	SEX HORMONE BINDING GLOBULIN	K268	SHBG EIA Cat. Nr K268	DE/CA37/IVD/13/11
35.	TROPONIN (T + I)	K291	Troponin I EIA Cat. Nr K291	DE/CA37/IVD/13/10
36.	IMMUNOGLOBULIN G	K271	Total IgG EIA Cat. Nr K271	DE/CA37/IVD/13/9
37.	IMMUNOGLOBULIN G SUBCLASS REAGENTS	K272 K274	IgG2 EIA Cat. Nr K272; IgG4 EIA Cat. Nr K274	DE/CA37/IVD/13/8
38.	IMMUNOGLOBULIN A	K275	Total IgA EIA Cat. Nr K275	DE/CA37/IVD/13/7
39.	IMMUNOGLOBULIN M	K277	Total IgM EIA Cat. Nr K277	DE/CA37/IVD/13/6
40.	RHEUMATOID/AUTOIMMUNE CONTROLS	KQ13 KQ14 KQ15	AutoQon AT immunoassay control set Cat. Nr KQ13; AutoQon ANA/ENA immunoassay control set Cat. Nr KQ14; AutoQon ACL immunoassay control set Cat. Nr KQ15	DE/CA37/IVD/13/5
41.	HORMONE CONTROLS	KQ21	HormoQon immunoassay control set Cat. Nr KQ21	DE/CA37/IVD/13/4
42.	TUMOUR MARKER CONTROLS	KQ22	OmaQon immunoassay control set Cat. Nr KQ22	DE/CA37/IVD/13/3
43.	CYFRA 21-1	K236	CYFRA 21-1 EIA	DE/CA37/IVD/13/45
44.	CANCER ANTIGEN 72-4	K244	CA 72-4 EIA	DE/CA37/IVD/13/46
45.	NEONATAL THYROID STIMULATING HORMONE	K201N	TSH-Neo EIA	DE/CA37/IVD/13/47
46.	ESTRIOL	K218	Free Estriol EIA	DE/CA37/IVD/13/48
47.	IMMUNOGLOBULIN E - MONOTEST/MONORESULT - MULTI AG	K200S	Specific IgE EIA	DE/CA37/IVD/13/49
48.	KAPPA AND LAMBDA CHAIN	K279K K279L	Free kappa lgg light chain EIA, Free lambda lgg light chain EIA	DE/CA37/IVD/13/50
49.	TRYPSIN NEONATAL	K242	Neonatal IRT EIA Cat. Nr K242	DE/CA37/IVD/13/51
50.	NEURON SPECIFIC ENOLASE	K234	NSE EIA Cat. Nr K234	DE/CA37/IVD/13/52

The above-mentioned medical products are marked with the CE symbol.
Die oben genannten medizinischen Produkte sind mit dem CE-Zeichen gekennzeichnet.

REPUBLICA MOLDOVA, mun. CHISINAU
CENTRU CONTRACTE SI FACTURI
"SANMEDICO"
IDNO 1003602...8154
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

Atlas Medical

Declaration Ref No: DC11-0011

CE Declaration of Conformity

We,
Atlas Medical

Head office: William James House, Cowley Road, Cambridge, CB0 4WX, UK
Tel: +910 858 1223 44
Fax: +524 858 1223 44
Email: info@atlas-site.co.uk

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

Declare our responsibility that the following product:

RPR Carbon Antigen

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, CB0 4WX, UK

Atlas Medical
Quality Diagnostic Products

Atlas Medical	First issue date	Date of review	Management approval	MRXDO10F. 10 08.02.2011
	Augsut-2003	06.11.2016		

REPUBLICA MOLDOVA, mun. CHISINAU
PENTRU CONTRACTE SI FACTURI
"SANMEDICO" S.R.L.
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

DECLARATION OF CONFORMITY

1) Manufacturer *(Name, department)*: **HiMedia Laboratories Pvt. Ltd.**

Address: 23 Vadhani Industrial Estate,LBS Marg, Mumbai - 86, MS, India

and

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.eu)

3) Product(s) *(groupnames /.)*:

Group	Group name	NL registration no.	No.
DCM&S	Dehydrated Culture Media & Supplements	NL-CA002-2013-26442	1
RPM	Ready Prepared Media Subgroups: Ready Prepared Plates, Ready Prepared Liquid & Solid Medium, Ready Prepared Slants,Ready Prepared Dual Media, HiDip Slides, HiSafe Blood Culturing System, Transport Medium w/ swabs, Viral Transport Medium w/ swabs, L.J.Medium Slants & Kits, Biochemical Kits for Mycobacteria, UTI Diagnostic Kits, Biochemical Identification Kits	NL-CA002-2013-26448	2
ESK	Epidemiological Screening Kit: Subgroups: Hi Aureus Confirmation Kits	NL-CA002-2012-24117	3
ASS	Antimicrobial Susceptibility Systems Subgroups: Sensitivity Discs-Single & Multi Discs MIC Strips: HiComb Strips & Ezy MIC Strips	NL-CA002-2013-26444	4
BDA	Bacteriological Differentiation Aids Subgroups: Readymade Stains, Indicators & Reagents in liquid, Differentiation Discs & Strips, HiDtect Rapid Identification Discs	NL-CA002-2013-26445	5
CCM	Cell Culture Media Subgroups: Karyotyping Media, Stem Cell Differentiation Media & Supplements, Stem Cell Freezing Medium, Stem Cell Differentiation Kits ,Viral Transport Medium, Balanced Salt Solutions, Antibiotic solutions, Animal Cell Culture Medium Liquid	NL-CA002-2013-26446	6
MBP	Molecular Biology Products Subgroups: DNA & RNA Isolation Kits, Latex Agglutination Kits, Haematology Kits, Density gradient Separation Medium, PCR Kits	NL-CA002-2013-26447	7

type and model numbers: see appendix

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, Registration nr., etc.)*:
Conformity assessment procedure for CE marking: *In vitro* Diagnostic Medical Device Directive, Annex III

Mumbai, India; 2019-04-22

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

Dr. G.M.Warke , Managing Director

(name; function and signature of manufacturer)

qualityaustria
Succeed with Quality

CERTIFICATE

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH awards this **quality**austria certificate to the following organisation:

This **quality**austria certificate confirms the application and further development of an effective

QUALITY MANAGEMENT SYSTEM
complying with the requirements of standard
ISO 9001:2015

HIMEDIA

HiMedia Laboratories Pvt. Ltd.
23, Vadhani Industrial Estate L.B.S.Marg,
Ghatkopar (W), Mumbai - 400086, Maharashtra, India

Unit-1: B-4-5-6, MIDC, Palkhed, Dindori, Nashik - 422 022, Maharashtra, India

Design and Development, Manufacturing and Supply of Biosciences Products for application in Microbiology (including Dehydrated culture Media, Antimicrobial Susceptibility Systems, Culture Media Bases and Bacteriological Diffrentiation Aids), Animal Tissue Culture, Plant Tissue Culture, Molecular Biology

The validity of the **quality**austria certificate will be maintained by annual surveillance audits and one renewal audit after three years.

Registration No.: 17285/0
Date of initial issue: 29 December 2015
Valid until: 21 November 2020

qualityaustria

IQNet

Vienna, 22 November 2017

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH,
AT-1010 Vienna, Zelinkagasse 10/3

Konrad Scheiber
General Manager

Dr. Mag. Arni Koubek
Specialist representative

The current validity of the certificate is documented exclusively on the Internet under
http://www.qualityaustria.com/en/cert EAC: 23

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IDNO 1003602
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