

TO WHOM IT MAY CONCERN

This declaration has been established for **GBG-MLD Moldova**

We, MACHEREY-NAGEL GMBH & CO KG, Neumann-Neander-Str, 6-8, 52355Düren, GERMANY, are Original Manufacturers of

- Filtration products
- Rapid Test products
- MEDI-TEST products
- Chromatography products

Our Authorized / (Non-)Exclusive Distributor in Moldova for the above mentioned products under MACHEREY-NAGEL brand, is the company

"GBG-MLD" S.R.L.
Tighina str.65, office 607
MD-2001,Chisinau,
Republic of Moldova

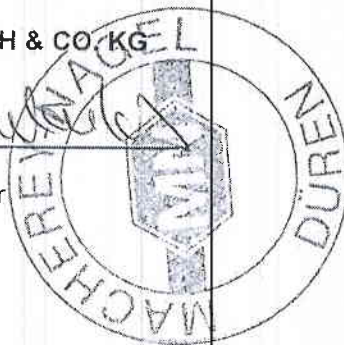
Explicitly, GBG-MLD is allowed to take part and submit bids in official tenders for the goods manufactured by us in GBG-MLD's own name, risk and on their own account. MACHEREY-NAGEL gives no warranty regarding the fulfilment of any signed contracts or conditions granted by GBG-MLD

This declaration will remain valid up to 31.12.2019 and will automatically end this date without any termination or expiration notice given. In no event shall this declaration be extended automatically.

Düren, 25.02.2019

MACHEREY-NAGEL GMBH & CO KG

Christos Evangelakakis
 Dr. Christos Evangelakakis
 International Sales Manager





EC Declaration of Conformity

EC Declaration of Conformity for In-vitro Diagnostic Products

The procedure for EC declaration of conformity was established on the basis of a full quality assurance system according to EN ISO 9001:2008 and EN ISO 13485:2012+AC:2012 according to the IVD directive 98/79/EC Annex IV, except chapters 4 and 6.



We

Name of manufacturer	MACHEREY-NAGEL GmbH & Co. KG
Address:	MACHEREY-NAGEL GmbH & Co. KG Neumann-Neander-Strasse 6-8 D - 52355 Dueren Germany

confirm that the following test strips for professional use

Name of product	Reference numbers
Medi-Test Glucose PN	93017; 930965
Medi-Test Glucose	93001; 93024
Medi-Test Glucose 3	93003; 93026
Medi-Test Glucose/Keton	93020; 93025
Medi-Test Protein 2	93004; 93027
Medi-Test Keton	93005; 93028
Medi-Test Nitrit	93006; 93029
Medi-Test Combi 2	93015; 93037
Medi-Test Urbi	93012
Medi-Test Combi 3	93050
Medi-Test Combi 3A	93007; 93030
Medi-Test Combi 5	93009; 93032
Medi-Test Combi 5N	93035; 93036
Medi-Test Combi 5S	93055
Medi-Test Combi 6	93018; 93078
Medi-Test Combi 6A	93013; 93034
Medi-Test Combi 7	93010; 93022
Medi-Test Combi 7L	93031
Medi-Test Combi 8L	93021
Medi-Test Combi 9	93011; 93023
Medi-Test Combi 10	93056
Medi-Test Combi 10L	93058; 93079
Medi-Test Combi 10 SGL	93067; 93077
Medi-Test URYXXON Stick 10	93068; 930872
Medi-Test Combi 11	93060; 930871
Medi-Test Mikroalbumin	930874



Type:

Urine Multi-constituent Test Strips
EDMS 11-70-02-02-00

Registration number:

DE/CA21/MACHEREY/2002/06/IVD/0001

Notified body:

TÜV Rheinland LGA Products GmbH
Tillystr. 2, 90431 Nürnberg

are manufactured in compliance with the European Directive 98/79/EC. The manufacturer is exclusively responsible for the declaration of conformity.

Düren, 22.09.2017



ppa. Dr. Markus Meusel (QAM, Manager Reg. Affairs)

www.mn-net.com



MACHEREY-NAGEL GmbH & Co. KG · Neumann-Neubauer-Str. 6-8 · 52355 Düren · Germany

DE / International

Tel.: +49 24 21 959-0
Fax: +49 24 21 959-100

E-mail: info@mn-net.com

CH:

Tel.: +41 82 365 55 00
Fax: +41 82 365 55 05

E-mail: sales-ch@mn-net.com

FR:

Tel.: +33 388 68 22 68
Fax: +33 388 61 76 88

E-mail: sales-fr@mn-net.com

US:

Tel.: +1 484 821 0084

Fax: +1 484 821 1272

E-mail: sales-us@mn-net.com



EC Declaration of Conformity

The procedure for EC declaration was established according to the IVD directive 98/79/EC on the basis of a full quality assurance system according to EN ISO 9001:2008 and EN ISO 13485:2012+AC:2012.



We

Name of manufacturer
 Address:

MACHEREY-NAGEL GmbH & Co. KG
 MACHEREY-NAGEL GmbH & Co. KG
 Neumann-Neander-Strasse 6-8
 D - 52355 Dueren
 Germany

confirm that the following product for professional use

Name of product
 Reference number, REF
 Type:
 Registration number:

Medi-Test Control
 930 38
 Other calibrators and standards (CC)
 EDMS 11-50-03-90-00
 DE/CA21/MACHEREY/2002/11/IVD/0007

is manufactured in compliance with the European Directive 98/79/EC.

Dueren, 12.02.2014

I.A. Markus Meusel (QA Manager)



EC DECLARATION OF CONFORMITY

according to Annex II of the IVD Directive 98/79/EC

EG Konformitätserklärung

gemäß Anhang II der IVD Richtlinie 98/79/EG

We hereby declare that the in vitro diagnostic medical device (IVD)

Hiermit erklären wir, dass das In-vitro-Diagnostikum (IVD)

URYXXON® 500
REF 930 080

URYXXON® 500
REF 930 080

GMDN Code: CT943 Instrument/analyser IVDs
EDMA IVD Classification: 21 05 Urine Analyser

GMDN Code: CT943 Instrumente/Analysatoren, IVD
EDMA IVD Klassifizierung: 21 05 Urin Analysgerät

is classified as *all other IVD* according to Annex II of the European directive 98/79/EC on in vitro diagnostic medical devices (IVDD)

gemäß Anhang II der Europäischen Richtlinie 98/79/EG über In-vitro-Diagnostika als *sonstiges IVD* klassifiziert ist

and complies with the essential requirements (Annex I) of the IVD Directive 98/79/EC.

und die Grundlegenden Anforderungen (Anhang I) der IVD Richtlinie 98/79/EG erfüllt.

In addition, it meets the requirements according to the following directive

Darüberhinaus erfüllt es die Anforderungen gemäß der folgenden Richtlinie

European directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2)

Europäische Richtlinie 2011/65/EU zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten (RoHS 2)

applied harmonized standards

angewandte Harmonisierte Normen

DIN EN ISO 9001:2008
DIN EN ISO 13485:2012 + AC:2012
DIN EN ISO 14971:2012

DIN EN ISO 18113-1:2010
DIN EN ISO 18113-3:2010
DIN EN 13512:2002
DIN EN 980:2008

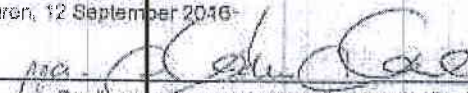
DIN EN ISO 15223-1:2013
DIN EN 62366:2008
DIN EN 62304:2006

DIN EN 61010-1:2010

DIN EN 61010-2-101:2003-09

DIN EN 61326-1:2013

Düren, 12 September 2016


Quality-management representative (authorized representative)

www.mn-net.com



MACHEREY-NAGEL GmbH & Co. KG · Neumann-Neander-Str. 6-8 · 52356 Düren · Germany

DE/International:

Tel.: +49 24 21 909-0
Fax: +49 24 21 909-100
E-mail: info@mn-net.com

CH:

Tel.: +41 62 358 65 00
Fax: +41 62 358 65 05
E-mail: sales-ch@mn-net.com

FR:

Tel.: +33 388 68 22 62
Fax: +33 388 61 78 88
E-mail: sales-fr@mn-net.com

US:

Tel.: +1 484 821 0904
Fax: +1 484 821 1272
E-mail: sales-us@mn-net.com



Certificate of Completion

this is to certify

Mr. Alexei Legun

has successfully completed

The technical maintenance training course

On

Urine Analysis

*URYXXON 200;
URYXXON RELAX;
URYXXON 500;*

Mars, 2006



President

MACHERY-NAGEL GMBH & CO.KG



ERMA INC.

2-31-6 Yushima, Bunkyo-ku, Tokyo 113-0034; Japan
Phone: 81-3-3818-6281 Fax: 81-3-3813-7301
E-mail address: trade@erma.co.jp.

MANUFACTURER'S AUTHORIZATION LETTER

Date Apr. 13, 2007

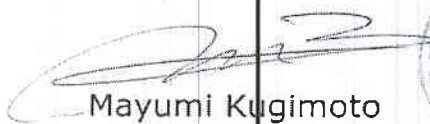
To whom it may concern,

WHEREAS, we ERMA INC., who are official and reputable manufacturers of medical and laboratory equipment as specified hereafter, hematology analyzer, biochemical analyzer, bilirubinmeter, hemoglobinmeter, microtome, having factories at 2-31-6 Yushima Bunkyo-ku, Tokyo 113-0034 Japan do hereby authorize:

GLOBAL BIOMARKETING GROUP MOLDOVA
Office 607, Tighina Str. 65 Chisinau, Moldova

To submit a bid in relation to the Bidding Document indicated above, the purpose of which is to provide the goods manufactured by us and to subsequently and sign the Contract.

Truly yours,


Mayumi Kugimoto
Manager, International Div.
ERMA INC.



Certificate of Completion

This is to certify

Mr. Alexei Legun

Has successfully completed

The technical maintenance training course

On

Fully Automatic Blood Cell Counter

PCE-210

Particle(Blood Cell)Counter

PCE-170/PCE-170N

Hemoglobin meter

HB-20N

March 24, 2005

H. Shimosaka

Hiroshi Shimosaka

President

ERMA, INC.





Awareness Technology, Inc.

Declaration of Conformity

Product Identification

Product name	Model/Type
Microstrip Reader	Stat Fax 300 series
	Stat Fax 4700 series
Chemistry Analyzer	Stat Fax1900 series
	ChemWell 2900 series
	Stat Fax 3300 series
	Stat Fax 4500 series
	ChemWell-T 4600 series
	ChemWell Fusion 4800 series
Microplate Reader	Stat Fax 2100 series
	Stat Fax 3200 series
	Stat Fax 4200 series
Incubator / Shaker	Stat Fax 2200 series
Microplate Washer	Stat Fax 2600 series
Electrolyte Analyzer	ISE 3900 series
Luminometer	LumiStat 4100 series
	LuMate 4400 series
	LumiStat 4900 series
Microplate Reader	ChroMate 4300 series

Manufacturer

Name : Awareness Technology, Inc.
 Address : 1935 SW Martin Hwy
 Palm City, Florida 34991
 Country : USA

Representative: Authorized Representative in Europe

Name : Emergo Europe
 Address : Molenstraat 15
 2513 BH The Hague
 Country : The Netherlands
 Telephone : +31 70 345 8570
 Fax Number : +31 70 346 7299

Means of Conformity

Awareness Technology, Inc. declares that the product listed is in conformity with the Annex III, essential requirements and provisions of Council Directive: 98/79/EC and is in conformance with the following standards: EN 61326-1 EMC / EN 61010-1 Safety

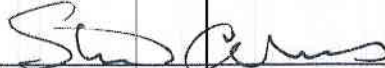
*Self-certified under the principles of ISO 13485:2003
 Registered Medical Device Quality System under ISO 13485:2003*

Place and date:

Awareness Technology, Inc.

October 26, 2016

Signature:
 Name:
 Title:


 Steve Andrus
 Quality Manager

CERTIFICATE OF REGISTRATION

This is to certify that the quality management system of:

Awareness Technology, Inc.

Main Site: 1935 SW Martin Highway

Palm City, Florida 34990 USA

Additional site: 2325 SW Martin Highway, Palm City, Florida 34990 USA

has been assessed by Intertek as conforming to the requirements of:

ISO 13485:2016

The quality management system is applicable to:

The design, development, manufacture and service of IVDD General Laboratory Instruments.

Additional site: Manufacturing, Quality Control, Shipping and Service.

Certificate Number:

9362-7

Initial Certification Date:

March 28, 2012

Certificate Issue Date:

March 27, 2018

Certificate Expiry Date:

March 27, 2021



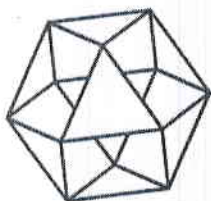
A handwritten signature in black ink, appearing to read "Calin Moldovean", written over a horizontal line.

Calin Moldovean

President

Intertek Testing Services NA Ltd.,
1829, 32nd avenue, Lachine, QC, H8T 3J1,
Canada





NSAI

Quality System Approval Certificate In Vitro Diagnostic Medical Devices Directive 98/79/EC

*The National Standards Authority of Ireland as a duly designated
Notified Body, (identification number 0050), for the purposes of the European Communities
(In Vitro Diagnostics Medical Devices) Regulations (S.I. No. 304 of 2001)*

APPROVES THE QUALITY SYSTEM APPLIED BY

Monobind Inc.

**100 North Pointe Drive
Lake Forest
CA 92630
USA**

For the Product Family

**Total and Free Prostate Specific Antigen (PSA and Free PSA) IVD, kit,
chemiluminescent immunoassay (CLIA) and enzyme immunoassay
(ELISA) and control**

GMDN Code: 54664, 54669

*On the basis of examination under the requirements of Annex IV, Section 3 of Directive 98/79/EC,
The use of the NSAI Notified Body identification number 0050 in conjunction with CE Marking of
Conformance for this product is hereby authorized.*

Registration Number:	304.1006
Original Registration:	28 October 2011
Last Amended on:	10 July 2018
Remains valid until:	27 October 2022

Signed:

Approved by:
Geraldine Larkin
Chief Executive Officer, NSAI

Approved by:
Susan Murphy
European Medical Device Operations Manager

**This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.
Details of the current product range and operational locations included within the scope of this approval can be obtained from NSAI**

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.



Monobind Inc.

The World Resource for Diagnostic Products

100 North Pointe Drive
Lake Forest, CA 92630
TEL 949.951.2665
FAX 949.951.3539

March 26, 2019

AUTHORIZATION LETTER

To whom it may concern:

Herewith, we Monobind Inc., 100 N. Pointe Dr., Lake Forest, CA 92630 USA, do confirm that "GBG-MLD" SRL with its address: Republic of Moldova, Chisinau, MD-2001, str. Tighina 65, office 607, is the exclusive distributor our AccuBind® ELISA and AccuLite® CLIA products and accessories in Moldova. IM Global Biomarketing Group is authorized to promote and supply our products, to contract for their delivery and take part in tenders with our products.

This authorization is valid until 31 March, 2020.

On behalf of the Monobind Inc.

Alicia Jerome Volkov
Marketing Director & Corporate Officer





Annex to Certificate Number: MD19.4585

**Certificate of Registration
of Quality Management System**

to I.S. EN ISO 13485:2012

The National Standards Authority of Ireland certifies that:
Monobind Inc.
100 North Pointe Drive
Lake Forest, CA 92630
USA

has been assessed and deemed to comply with the requirements of the above standard in respect of the scope of operations given below:

Scope of Registration:

The Design, Manufacture and Distribution of In-Vitro Diagnostic Medical Device Immunoassays, and Related Reagent Products and Equipment

Activity

Headquarters, Design, Manufacture

Location

Monobind Inc.
100 North Pointe Drive
Lake Forest, CA 92630
USA

The Design, Manufacture and Distribution of In-Vitro Diagnostic Medical Device Immunoassays, and Related Reagent Products and Equipment

Manufacture, Design

File No.: MD19.4585

Monobind Inc.
103 North Pointe Drive
Lake Forest, CA 92630
USA
File No.: MD19.4585/A

Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.4585)

**Verified by:
Operations Manager**

Approved by:
Geraldine Larkin
Chief Executive Officer

Approved by:
Susan Murphy
European Medical Device
Operations Manager

Registration Number: MD19.4585
Certification Granted: May 18, 2010
Effective Date: Oct 29, 2017
Expiry Date: Oct 28, 2020



National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3900

DECLARATION OF CONFORMITY

1) Manufacturer (Name, department): **Monobind Inc.**
Address: **100 North Pointe, LAKE FOREST, CA 92630. UNITED STATES**

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) (name, type or model/batch number, etc.):

Immunoassay products:
ELISA,
CLIA,
Control,
Instruments
(see appendix)

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

<u>Title</u>	<u>Document No.</u>
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**
Registration nr. : **NL- CA002-22758 and NL- CA002-22762**

Lake Forest, USA; 2013-09-16

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

Maarn, NL; 2013-09-16
(Place & date of issue (yyyy-mm-dd))


Tony Shatola; QA Director, Monobind Inc.
(name; function and signature of manufacturer)


Olga Teirinck; Consultant, CEpartner4U BV
(name; function and signature of authorized representative)

Appendix

List of devices.

Device types	Item# Acculink®	Item# QSure®	Item# Control	Item# ent	ELISA Microwells	CLIA Microwells	EUJMS code	Risk Class	First date of CE-marking
Thyroid									
Total Triiodothyronine (T3) Test System	125-300	175-300					12.04.01.05.00	Low	2005-11-11
Free Triiodothyronine (FT3) Test System	1325-300	1375-300					12.04.01.01.00	Low	2005-11-11
Thyroxine (T4) Test System	225-300	275-300					12.04.01.07.00	Low	2005-11-11
Free Thyroxine (FT4) Test System	1225-300	1275-300					12.04.01.02.00	Low	2005-11-11
Thyrotropin (TSH) Test System	325-300	375-300					12.04.01.11.00	Low	2005-11-11
Rapid TSH Test System	6025-300	6075-300					12.04.01.11.00	Low	2010-06-29
T3-Uptake (T3U) Test System	525-300	575-300					12.04.01.06.00	Low	2005-11-11
Thyroxine-Binding Globulin (TBG) Test System	3525-300	3575-300					12.04.01.09.00	Low	2005-11-11
Thyroglobulin (Tg) Test System	2225-300	2275-300					12.04.01.08.00	Low	2005-11-11
Total Thyroxine (TT4), Total Triiodothyronine (TT3) & Thyrotropin (TSH) Test System	6625-300	6675-300					12.04.01.04.00	Low	2005-11-11
Panel (VAST) Test System	8125-300	8175-300					12.04.01.01.00	Low	2010-06-29
Total Thyroxine (TT4 S/S) Test System	8225-300	8275-300					12.04.01.01.00	Low	2010-06-29
Free Thyroxine (FT4), Free Triiodothyronine (FT3) & Thyroid Stimulating Hormone Free Thyroid Panel (VAST) Test System	7025-300	7075-300					12.04.01.01.00	Low	2010-06-29
Neonatal Thyroid & Genetics									
Neonatal TSH (N-TSH) Test System	3425-300	3475-300					12.04.01.90.00	Low	2005-11-11
Neonatal (N-T4) Thyroxine Test System	2625-300	2675-300					12.04.01.12.00	Low	2005-11-11
Neonatal TPOHP (N-TPOHP) Test System	5525-300	5575-300					12.05.01.07	Low	2008-02-01
Neonatal TBG (N-TBG) Test System	8925-300	8975-300					12.04.01.09.00	Low	2013-09-16
Autoimmune Thyroid									
Anti-Thyroglobulin (Anti-Tg) Test System	1025-300	1075-300					12.10.03.04.00	Low	2005-11-11
Anti-Thyroperoxidase (Anti-TPO) Test System	1125-300	1175-300					12.10.03.01.00	Low	2005-11-11
Fertility & Prenatal									
Luteinizing Hormone (LH) Test System	625-300	675-300					12.05.01.05.00	Low	2005-11-11
Folicle Stimulating Hormone (FSH) Test System	425-300	475-300					12.05.01.04.00	Low	2005-11-11
Prolactin Hormone (PRL) Test System	725-300	775-300					12.05.01.08.00	Low	2005-11-11
Prolactin Hormone Sequential (PRLs) Test System	6025-300	6075-300					12.05.01.08.00	Low	2005-11-11
B-Human Chorionic Gonadotropin (hCG) Test System	825-300	875-300					12.05.02.05.00	Low	2005-11-11
B-Human Chorionic Gonadotropin Extended Range (Ext. Range hCG) Test System	8825-300	8875-300					12.05.02.05.00	Low	2013-09-16
Rapid B-Human Chorionic Gonadotropin (Rapid	3325-300						12.05.02.05.00	Low	2005-11-11

Device types	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells	Item# QSure® Control	Item# Instrument	EDMS code	Risk Class	First date of CE-marking
(hCG) Test System							
Human Chorionic Gonadotropin (hCG) , Human Prolactin (hPRL), Human Luteinizing Hormone (hLH), Folicide Stimulating Hormone (FSH) Fertility Panel (VAST) Test System	8325-300	8375-300			12.05.01.90.00	Low	2006-08-24
Alpha-Fetoprotein (AFP), Human Chorionic Gonadotropin (hCG), Unconjugated Estiol (u-E3) Triple Screen (VAST) Test System	8525-300	6575-300			12.05.01.90.00	Low	2010-06-29
Pregnancy Associated Plasma Protein - A (PAPP-A) Test System	7925-300	7975-300			12.05.02.10.00	Low	2013-09-16
Steroid							
Cortisol Test System	3625-300	3675-300			12.06.02.04.00	Low	2005-11-11
DHEA-S Test System	5125-300	5175-300			12.05.01.02.00	Low	2010-06-29
Dehydroepiandrosterone (DHEA) Test System	7425-300	7475-300			12.05.01.02.00	Low	2011-09-26
Estradiol (E2) Test System	4925-300	4975-300			12.05.01.03.00	Low	2010-06-29
Unconjugated Estiol (u-E3) Test System	5025-300	5075-300			12.05.02.02.00	Low	2010-06-29
Progesterone Test System	4825-300	4875-300			12.05.01.06.00	Low	2010-06-29
Sex Hormone Binding Globulin (SHBG) Test System	9125-300	9175-300			12.05.01.09.00	Low	2013-09-16
Testosterone Test System	3725-300	3775-300			12.05.01.10.00	Low	2007-11-01
Free Testosterone Test System	5325-300	5375-300			12.05.01.10.00	Low	2010-06-29
17α-OH Progesterone Test System	5225-300	5275-300			12.05.01.07.00	Low	2010-06-29
17α-OH Progesterone - SI Test System	9925-300	9975-300			12.05.01.07.00	Low	2010-10-18
Growth & Bone Metabolism							
Growth Hormone (hGH) Test System	1725-300	1775-300			12.06.04.02.00	Low	2005-11-11
Parathyroid Hormone (PTH) Test System	9225-300	9275-300			12.06.03.13.00	Low	2011-09-26
25-Hydroxyvitamin D3 (Vitamin D3) Test System	7725-300	7775-300			12.06.03.10.00	Low	2011-09-26
Diabetes							
Insulin Test System	2425-300	2475-300			12.06.01.03.00	Low	2005-11-11
Rapid Insulin Test System	5825-300				12.06.01.03.00	Low	2010-06-29
C-Peptide Test System	2725-300	2775-300			12.06.01.01.00	Low	2005-11-11
Insulin - C-Peptide (VAST)	7325-300	7375-300			12.06.01.03.00	Low	2005-11-11
Cardiac Markers							
CK-MB Test System	2925-300	2975-300			12.13.01.02.00	Low	2005-11-11
Troponin I (cTnI) Test System	3825-300	3875-300			12.13.01.07.00	Low	2005-11-11
Digoxin (DIG) Test System	925-300	975-300			12.06.01.01.00	Low	2005-11-11
High Sensitivity CRP (hs-CRP) Test System	3125-300	3175-300			12.13.01.90.00	Low	2005-11-11
Myoglobin Test System	3225-300	3275-300			12.13.01.05.00	Low	2005-11-11

Device types	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells	Item# QSure® Control	Item# Instrument	EDMS code	Risk Class	First date of CE-marking
Infectious Diseases							
Anti-H. Pylori IgG Test System	1425-300	1475-300			15.01.04.03.00	Low	2005-11-11
Anti-H. Pylori IgM Test System	1525-300	1575-300			15.01.04.03.00	Low	2005-11-11
Anti-H. Pylori IgA Test System	1625-300	1675-300			15.01.04.03.00	Low	2005-11-11
Cancer Markers							
Alpha-Fetoprotein (AFP) Test System	1925-300	1975-300			12.03.90.01.00	Low	2005-11-11
CA-125 Test System	3025-300	3075-300			12.03.01.05.00	Low	2005-11-11
CA 15-3 Test System	5625-300	5675-300			12.03.01.02.00	Low	2010-06-29
CA -19-9 Test System	3925-300	3975-300			12.03.01.03.00	Low	2005-11-11
Carcinoembryonic Antigen (CEA) Test System	1825-300	1875-300			12.03.01.31.00	Low	2005-11-11
Next Generation Carcinoembryonic Antigen (CEA) Test System	4625-300	4675-300			12.03.01.31.00	Low	2010-06-29
Free β-Subunit Human Chorionic Gonadotropin (fβHCG) Test System	2025-300	2075-300			12.03.01.90.00	Low	2005-11-11
Allergy & Anaemia							
Ferritin Test System	2825-300	2875-300			12.07.01.02.00	Low	2005-11-11
Folate Test System	7525-300	7575-300			12.07.01.03.00	Low	2010-06-29
Immunoglobulin E (IgE) Test System	2525-300	2575-300			12.02.01.02.00	Low	2005-11-11
Transferrin Soluble Receptor (sTfR) Test System	8625-300	8675-300			12.07.01.06.00	Low	2010-06-29
Vitamin B-12 (B12) Test System	7625-300	7675-300			12.07.02.04.00	Low	2011-09-26
Folate, Vitamin B-12 (VAST) Test System	7825-300	7875-300			12.07.01.00.00	Low	2013-09-16
Miscellaneous Controls							
Anti-Thyroglobulin (Anti-Tg), Anti-Thyroxinase (Anti-TPO) Control - Positive & Negative			AIT-101		12.50.01.16.00	Low	2010-06-29
High Level Fertility Control - Single Level - Progesterone, Estradiol, Human Chorionic Gonadotropin			FC-300		12.50.01.16.00	Low	2010-06-29
Maternal Control - Tri Level - Human Chorionic Gonadotropin, Free Beta Human Chorionic Gonadotropin Subunit, Alpha Feta Protein, Estradiol			MC-300		12.50.01.16.00	Low	2010-06-29
Thyroglobulin (Tg) Control - Tri Level			TG-300		12.50.01.16.00	Low	2010-06-29
H. Pylori IgG Control - Positive & Negative			HPY-IgG-300		12.50.01.16.00	Low	2010-06-29
H. Pylori IgM Control - Positive & Negative			HPY-IgM-300		12.50.01.16.00	Low	2013-09-16
H. Pylori IgA Control - Positive & Negative			HPY-IgA-300		12.50.01.16.00	Low	2013-09-16
Thyroid Binding Globulin (TBG) Control - Tri-Level			TBG-300		12.50.01.16.00	Low	2013-09-16
Miscellaneous Instruments							
Autoplex ELISA & CLIA Analyzer				IN006	21.02.10.01	Low	2010-06-29
Autoplex Generation 2 ELISA & CLIA Analyzer				IN006-2	21.02.10.01	Low	2013-09-16
Lumax CLIA Analyzer				IN001	21.02.10.01	Low	2006-08-24
Nso-Lumax CLIA Analyzer				IN010	21.02.10.01	Low	2011-09-26



Declaration of Conformity

2013-09 DoC_MB_v08

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Device types	Item# AccuBind® ELISA Microwells	Item# AccuLife® CLIA Microwells	Item# QSure® Control	Item# Instrum ent	EDMS code	Risk Class	First date of CE-marking
Impulse 2 CLIA Analyzer				IN005	21.02.10.01	Low	2006-08-24
Impulse 3 CLIA Analyzer				IN007	21.02.10.01	Low	2010-06-29
Lumax36 CLIA Analyzer				IN004	21.02.10.01	Low	2007-03-01
Lumatic CLIA Analyzer				IN008	21.02.10.01	Low	2011-09-26
Eldex 3.8 ELISA Analyzer				IN003	21.02.10.01	Low	2007-09-10
Nso-Eldex ELISA Analyzer				IN009	21.02.10.01	Low	2011-09-26
PrisMatic ELISA Analyzer				IN013	21.02.10.01	Low	2013-09-16
Plate Washer Microplate Washer				IN002	21.02.10.01	Low	2010-06-29



EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
CRP Latex kit	850100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

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

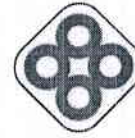
- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.

Eddy Velthuis
Technical Director





LORNE
LABORATORIES

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
RF Latex kit	830100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

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

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.

Eddy Velthuis
Technical Director



File No A12241
ISO 13485:2003; ISO 9001:2008

Lorne Laboratories Limited
Unit 1 Cutbush Park Industrial Estate
Danehill, Lower Earley
Berkshire RG6 4UT United Kingdom

Tel: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
Email: info@lornelabs.com
www.lornelabs.com

Registered office as above. Registered in England No. 04540797. VAT No. 800 3655 66



EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
ASO Latex kit	031100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

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

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.

Eddy Velthuis
Technical Director





Dia.Pro
Diagnostic
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Letter of Authorization

We, "Dia.Pro Diagnostic Bioprobes S.r.l." located at Via G. Carducci, Nr. 27 – Sesto San Giovanni (Milan) 20099, Italy, authorize

GLOBAL BIOMARKETING GROUP – MOLDOVA SRL
Str. Tighina 65, Oficiu 607
MD-2001 CHISINAU
REP. MOLDOVA

as our exclusive distributor for the territory of the Republic of Moldova, to participate in various tenders with **Dia.Pro** ELISA products.

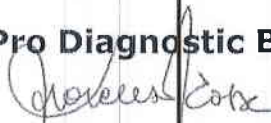
We, Dia.Pro Diagnostic Bioprobes S.r.l shall supply our distributor GLOBAL BIOMARKETING GROUP – MOLDOVA SRL with all products in strict compliance with the existing "Distribution Agreement" rev.0117 valid until 31-Dec-2020, with possibility of renewal upon agreement between both parties for an additional period.

Dia.Pro Diagnostic Bioprobes S.r.l will grant the supply of all awarded tenders until their natural expiry, of which a documental proof has to be provided to Dia.Pro by the distributor GLOBAL BIOMARKETING GROUP – MOLDOVA SRL.

Sincerely yours,

Date: **Milan, 31-January-2018**

Dia.Pro Diagnostic Bioprobes S.r.l.


DIA.PRO.
DIAGNOSTIC BIOPROBES S.r.l.

Dr.ssa Fiorenza Scozzesi
Legal Representative



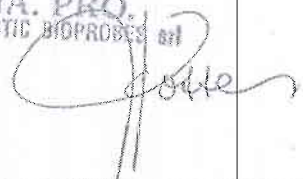
Dia.Pro
Diagnostic
Bio*Probes*

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	HBs Ag Confirmation CODES: SCONF.CE (20 tests) SCONF.CE.40 (40 tests)
CLASSIFICATION	ANNEX II – LIST A
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED
PRODUCT MEETS THE PROVISIONS OF THE COUNCIL
DIRECTIVE 98/79/EC
FOR IN VITRO DIAGNOSTIC DEVICES.**

NOTIFIED BODY (EC) CERTIFICATE(S)	AEMPS – n° 0318 <ul style="list-style-type: none">• FULL QUALITY ASSURANCE SYSTEM N° 2003 12 0388 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318• DESIGN CERTIFICATE N° 2006 11 0511 ED RELEASED BY EC NOTIFIED BODY N° 0318• UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318
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PLACE & DATE OF FIRST ISSUE	MILANO – DECEMBER 2006
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	 DIA.PRO DIAGNOSTIC BIOPROBES s.r.l.

Rev: 12/2013



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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 - 20099 SESTO SAN GIOVANNI (MILANO) - ITALY
PRODUCT	HBs Ab CODE: SAB.CE (96 tests)
CLASSIFICATION	ANNEX II - LIST A
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED
PRODUCT MEETS THE PROVISIONS OF THE COUNCIL
DIRECTIVE 98/79/EC
FOR IN VITRO DIAGNOSTIC DEVICES.**

NOTIFIED BODY (EC) CERTIFICATE(S)	AEMPS - n° 0318 <ul style="list-style-type: none">• FULL QUALITY ASSURANCE SYSTEM N° 2003 12 0388 CT (in accordance with Annex IV - except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318• DESIGN CERTIFICATE N° 2003 12 0390 ED RELEASED BY EC NOTIFIED BODY N° 0318• UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318
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PLACE & DATE OF FIRST ISSUE	MILANO - JANUARY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) - DECEMBER 2013
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	 DIA. PRO. DIAGNOSTIC BIOPROBES srl

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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	HBc Ab CODE: BCAB.CE (96 tests)
CLASSIFICATION	ANNEX II – LIST A
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED
PRODUCT MEETS THE PROVISIONS OF THE COUNCIL
DIRECTIVE 98/79/EC
FOR IN VITRO DIAGNOSTIC DEVICES.**

NOTIFIED BODY (EC) CERTIFICATE(S)	AEMPS – n° 0318 <ul style="list-style-type: none">• FULL QUALITY ASSURANCE SYSTEM N° 2003 12 0388 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318• DESIGN CERTIFICATE N° 2003 12 0391 ED RELEASED BY EC NOTIFIED BODY N° 0318• UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318
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PLACE & DATE OF FIRST ISSUE	MILANO – JANUARY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	 DIA.PRO DIAGNOSTIC BIOPROBES srl

Rev: 12/2013



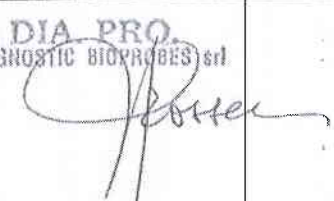
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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	HBe Ag&Ab CODE: HBE.CE (96 tests)
CLASSIFICATION	ANNEX II – LIST A
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED
 PRODUCT MEETS THE PROVISIONS OF THE COUNCIL
 DIRECTIVE 98/79/EC
 FOR IN VITRO DIAGNOSTIC DEVICES.**

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	<ul style="list-style-type: none"> • FULL QUALITY ASSURANCE SYSTEM N° 2003 12 0388 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318 • DESIGN CERTIFICATE N° 2004 03 0425 ED RELEASED BY EC NOTIFIED BODY N° 0318 • UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – APRIL 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	 DIA.PRO DIAGNOSTIC BIOPROBES s.r.l.

Rev: 12/2013



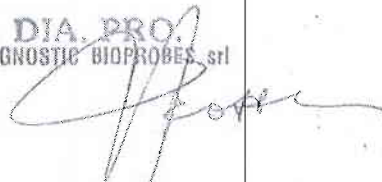
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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	HCV Ab CODES: CVAB.CE (192 tests) CVAB.CE.96 (96 tests) CVAB.CE.480 (480 tests) CVAB.CE.960 (960 tests) CVAB.CE.DB (192 tests)
CLASSIFICATION	ANNEX II – LIST A
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED
 PRODUCT MEETS THE PROVISIONS OF THE COUNCIL
 DIRECTIVE 98/79/EC
 FOR IN VITRO DIAGNOSTIC DEVICES.**

NOTIFIED BODY (EC) CERTIFICATE(S)	AEMPS – n° 0318 <ul style="list-style-type: none"> • FULL QUALITY ASSURANCE SYSTEM N° 2003 12 0388 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318 • DESIGN CERTIFICATE N° 2003 12 0392 ED RELEASED BY EC NOTIFIED BODY N° 0318 • UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318
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PLACE & DATE OF FIRST ISSUE	MILANO – JANUARY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	 DIA.PRO DIAGNOSTIC BIOPROBES srl

Rev: 12/2013



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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	HDV Ab CODE: DAB.CE (96 tests)
CLASSIFICATION	ANNEX II – LIST A
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED
PRODUCT MEETS THE PROVISIONS OF THE COUNCIL
DIRECTIVE 98/79/EC
FOR IN VITRO DIAGNOSTIC DEVICES.**

NOTIFIED BODY (EC) CERTIFICATE(S)	AEMPS – n° 0318 <ul style="list-style-type: none">• FULL QUALITY ASSURANCE SYSTEM N° 2003 12 0388 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318• DESIGN CERTIFICATE N° 2003 12 0393 ED RELEASED BY EC NOTIFIED BODY N° 0318• UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318
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PLACE & DATE OF FIRST ISSUE	MILANO – JANUARY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	 DIA. PRO. DIAGNOSTIC BIOPROBES srl

Rev: 12/2013



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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	Chlamydia Trachomatis IgG CODE: CTG.CE (96 tests)
CLASSIFICATION	ANNEX II – LIST B
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED
PRODUCT MEETS THE PROVISIONS OF THE COUNCIL
DIRECTIVE 98/79/EC
FOR IN VITRO DIAGNOSTIC DEVICES.**

NOTIFIED BODY (EC) CERTIFICATE(S)	AEMPS – n° 0318 <ul style="list-style-type: none">• FULL QUALITY ASSURANCE SYSTEM N° 2004 05 0442 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318• UNI EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318
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PLACE & DATE OF FIRST ISSUE	MILANO – MAY 2009
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	 DIA. PRO, DIAGNOSTIC BIOPROBES srl

Rev: 12/2013




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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	Chlamydia Trachomatis IgM CODE: CTM.CE (96 tests)
CLASSIFICATION	ANNEX II – LIST B
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED
PRODUCT MEETS THE PROVISIONS OF THE COUNCIL
DIRECTIVE 98/79/EC
FOR IN VITRO DIAGNOSTIC DEVICES.**

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	<ul style="list-style-type: none">• FULL QUALITY ASSURANCE SYSTEM N° 2004 05 0442 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318• UNI EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – MAY 2009
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	<p>DIA. PRO. DIAGNOSTIC BIOPROBES srl</p> 

Rev: 12/2013



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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	HSV1&2 IgM CODE: HSV.M.CE (96 tests)
CLASSIFICATION	GENERAL IVD
CONFORMITY ASSESSMENT ROUTE	SELF CERTIFICATION

WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC FOR IN VITRO DIAGNOSTIC DEVICES.

ISO CERTIFICATE(S)	UNI CEI EN ISO 9001–Nr 50 100 5931/A UNI CEI EN ISO 13485–Nr 50 100 5931/B RELEASED BY CERTIFICATION BODY TÜV Italia S.r.l.
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PLACE & DATE OF FIRST ISSUE	MILANO – OCTOBER 2004
PLACE & DATE OF CURRENT ISSUE	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	 DIA.PRO DIAGNOSTIC BIOPROBES S.R.L.

Rev: 12/2013



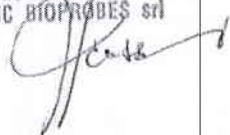
Dia.Pro
Diagnostic
Bio**Probes**

EC DECLARATION OF CONFORMITY

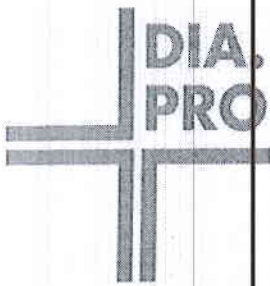
MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	HSV1&2 IgG CODE: HSVG.CE (96 tests)
CLASSIFICATION	GENERAL IVD
CONFORMITY ASSESSMENT ROUTE	SELF CERTIFICATION

WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS
THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC
FOR IN VITRO DIAGNOSTIC DEVICES.

ISO CERTIFICATE(S)	UNI CEI EN ISO 9001–Nr 50 100 5931/A UNI CEI EN ISO 13485–Nr 50 100 5931/B RELEASED BY CERTIFICATION BODY TÜV Italia S.r.l.
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PLACE & DATE OF FIRST ISSUE	MILANO – MARCH 2004
PLACE & DATE OF CURRENT ISSUE	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	 DIA. PRO. DIAGNOSTIC BIOPROBES srl

Rev: 12/2013



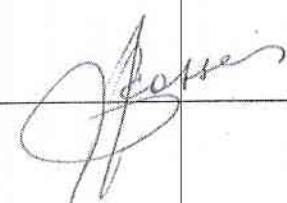
Dia.Pro
Diagnostic
Bio**Probes**

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	CMV IgM CODE: CMVM.CE (96 tests)
CLASSIFICATION	ANNEX II – LIST B
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED
PRODUCT MEETS THE PROVISIONS OF THE COUNCIL
DIRECTIVE 98/79/EC
FOR IN VITRO DIAGNOSTIC DEVICES.**

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	<ul style="list-style-type: none">• FULL QUALITY ASSURANCE SYSTEM N° 2004 05 0442 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318• UNI EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – MAY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	<p style="text-align: center;">DIA. PRO. DIAGNOSTIC BIOPROBES srl</p> 

Rev: 12/2013



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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	CMV IgG CODE: CMVG.CE (96 tests)
CLASSIFICATION	ANNEX II – LIST B
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED
PRODUCT MEETS THE PROVISIONS OF THE COUNCIL
DIRECTIVE 98/79/EC
FOR IN VITRO DIAGNOSTIC DEVICES.**

NOTIFIED BODY (EC) CERTIFICATE(S)	AEMPS – n° 0318 <ul style="list-style-type: none">FULL QUALITY ASSURANCE SYSTEM N° 2004 05 0442 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318UNI EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318
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PLACE & DATE OF FIRST ISSUE	MILANO – MAY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	<p>DIA. PRO. DIAGNOSTIC BIOPROBES srl</p>

Rev: 12/2013



Dia.Pro
Diagnostic
Bio*Probes*

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	TOXO IgM CODE: TOXOM.CE (96 tests)
CLASSIFICATION	ANNEX II – LIST B
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED
PRODUCT MEETS THE PROVISIONS OF THE COUNCIL
DIRECTIVE 98/79/EC
FOR IN VITRO DIAGNOSTIC DEVICES.**

NOTIFIED BODY (EC) CERTIFICATE(S)	AEMPS – n° 0318 <ul style="list-style-type: none">• FULL QUALITY ASSURANCE SYSTEM N° 2004 05 0442 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318• UNI EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318
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PLACE & DATE OF FIRST ISSUE	MILANO – MAY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	DIA. PRO. DIAGNOSTIC BIOPROBES srl

Rev: 12/2013



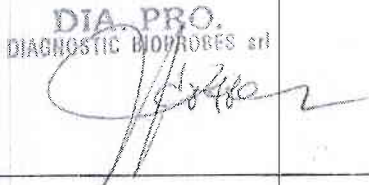
Dia.Pro
Diagnostic
Bio**Probes**

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	TOXO IgG CODE: TOXOG.CE (96 tests)
CLASSIFICATION	ANNEX II – LIST B
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED
PRODUCT MEETS THE PROVISIONS OF THE COUNCIL
DIRECTIVE 98/79/EC
FOR IN VITRO DIAGNOSTIC DEVICES.**

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	<ul style="list-style-type: none">• FULL QUALITY ASSURANCE SYSTEM N° 2004 05 0442 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318• UNI EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – MAY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	

Rev: 12/2013



Dia.Pro
Diagnostic
 Bio**Probes**

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	HP IgG CODE: HPG,CE (96 tests)
CLASSIFICATION	GENERAL IVD
CONFORMITY ASSESSMENT ROUTE	SELF CERTIFICATION

WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS
 THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC
 FOR IN VITRO DIAGNOSTIC DEVICES.

ISO CERTIFICATE(S)	UNI CEI EN ISO 9001–Nr 50 100 5931/A UNI CEI EN ISO 13485–Nr 50 100 5931/B RELEASED BY CERTIFICATION BODY TÜV Italia S.r.l.
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PLACE & DATE OF FIRST ISSUE	MILANO – MARCH 2004
PLACE & DATE OF CURRENT ISSUE	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	

Rev: 12/2013

ВЕКТОР



ОГРН 1025404347550
ИНН 5433104584/ КПП 543301001
р/с 40702810244020101090
в Сибирском банке ПАО Сбербанк,
БИК 045004641
корр. сч. 30101810500000000641
ОКВЭД 21.20.2, 72.11 / ОКПО 23548172

от 18.11.2019 № РК-151

АО "Вектор-Бест"
630117, г. Новосибирск, а/я 492
тел.: (383) 227-73-60, 332-36-34
тел./факс: 332-67-49, 332-67-52
e-mail: vbmarket@vector-best.ru
Internet: http://www.vector-best.ru

«GBG-MLD» SRL
Республики Молдова, г. Кишинев,
ул. Тигина, 65, оф. 607
Чайковскому Т.К.

Авторизация от производителя

Акционерное общество «Вектор-Бест» (Российская Федерация, 630559, Новосибирская область, рабочий поселок, Кольцово, Научно-производственная зона, корпус 36, к. 211) официально удостоверяет, что «GBG-MLD» SRL (Республика Молдова, г. Кишинев, ул. Тигина, 65, оф. 607) имеет право участвовать от имени АО «Вектор-Бест» в тендерах, проводимых медицинскими учреждениями Республики Молдова и осуществлять рекламно-информационное сопровождение.

Срок действия авторизации по 31 декабря 2020 года включительно.

Коммерческий директор АО «Вектор-Бест»  Гусев Ю.М.



Сертификат

mdc medical device certification GmbH
удостоверяет, что на предприятии

ВЕКТОР



АО «Вектор-Бест»
630559, Новосибирская область, р.п. Кольцово,
Научно-производственная зона, корпус 36, к. 211,
Российская Федерация

с производственными площадками согласно приложению к Сертификату применительно к областям

проектирование и разработка, производство и реализация
медицинских изделий in-vitro диагностики
(ПЦР, ИФА, биохимия)

была введена и применяется

СИСТЕМА УПРАВЛЕНИЯ КАЧЕСТВОМ

Проведенная проверка системы управления качеством показала,
что данная система соответствует требованиям стандарта:

EN ISO 13485

Изделия медицинские – Системы менеджмента качества –
Регулирующие системные требования

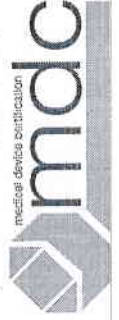
EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Дата выдачи	2018-07-13
Срок действия до	2020-07-03
Регистрационный №	D1213100017
Отчет №	P18-00489-117996
Штутгарт, Германия	2018-07-13

Руководитель сертификационного органа



mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10



mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10

Приложение к Сертификату

№ D1213100017

от 2018-07-13

Стр. 1 из 1

Месторасположение	Область действия
АО «Вектор-Бест», ул. Арбузов, 44, 630117, г. Новосибирск, Российская Федерация	проектирование и разработка, производство медицинских изделий in-vitro диагностики
АО «Вектор-Бест», 630559, Новосибирская область, р.п. Кольцово, Научно-производственная зона, корпус 36, Российская Федерация	проектирование и разработка, производство медицинских изделий in vitro диагностики
АО «Вектор-Бест», ул. Пасечная, 3, 630117, г. Новосибирск, Российская Федерация	проектирование и разработка, производство медицинских изделий in vitro диагностики

Руководитель сертификационного органа

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10

EC DECLARATION OF CONFORMITY

ZAO "Vector-Best" hereby ensures under own responsibility and declares that the products listed on pages 2-4 are in conformity with applicable provisions and fulfill the essential requirements of Annex I Directive 98/79/EC of 27 October 1998 regarding in vitro diagnostic medical devices.

Classification of products:

Other devices (all devices except Annex II and self-testing devices)

Conformity assessment procedure:

Annex III (not including section 6).

Manufacturer:

ZAO "Vector-Best"
Address: AHC, Koltsovo,
Novosibirsk Region, 630559, Russia,
Tel.: +7 (383) 363 20 60,
Fax: +7 (383) 363 35 55

European authorized representative:

Bioron GmbH,
Rheinhorststr. 18, D-67071
Ludwigshafen, Germany.
tel.: +49 (0) 621 5720 915,
fax: +49 (0) 621 5720 916

Date: 2013/04/12

Murat Khusainov
General Director ZAO «Vector-Best»



No.	Product name	Identification data	REF
1.	Vectohep A-IgM	ELISA kit for determination of IgM to hepatitis A virus	D-0352
2.	Vectohep A-IgG	ELISA kit for quantitative and qualitative determination of IgG to hepatitis A virus	D-0362
3.	Vectohep ITV-IgG	ELISA kit for determination of IgG to IT virus	D-0802
4.	Vectohep E-IgG	ELISA kit for determination of IgG to hepatitis E virus	D-1056
5.	Vectohep E-IgM	ELISA kit for determination of IgM to hepatitis E virus	D-1058
6.	Vectohep G-IgG	ELISA kit for determination of IgG to hepatitis G virus	D-1252
7.	LymeBest-IgG	ELISA kit for determination of IgG to infectious borreliosis agents	D-1452
8.	LymeBest-IgM	ELISA kit for determination of IgM to infectious borreliosis agents	D-1454
9.	RecombiBest antipallidum-IgG	ELISA kit for determination of IgG to Treponema pallidum	D-1852
10.	RecombiBest antipallidum-total antibodies	ELISA kit for determination of total antibodies to Treponema pallidum	D-1856
11.	RecombiBest antipallidum-IgM	ELISA kit for determination of IgM to Treponema pallidum	D-1858
12.	RecombiBest antipallidum-total antibodies	ELISA kit for determination of total antibodies to Treponema pallidum	D-1857
13.	VectoHSV-1,2 - IgG	ELISA kit for determination of IgG to herpes simplex virus types 1 and 2	D-2152
14.	VectoHSV - IgM	ELISA kit for determination of IgM to herpes simplex virus types 1 and 2	D-2154
15.	VectoHHV-8 - IgG	ELISA kit for determination of IgG to human herpes virus type 8	D-2160
16.	VectoHHV-6 - IgG	ELISA kit for determination of IgG to human herpes virus type 6	D-2166
17.	Ureaplasma urealyticum - IgG-EIA-BEST	ELISA kit for determination of IgG to Ureaplasma urealyticum antigens	D-2254
18.	Ureaplasma urealyticum - IgA-EIA-BEST	ELISA kit for determination of IgA to Ureaplasma urealyticum antigens	D-2258
19.	VectorParotitis-IgG	ELISA kit for determination of IgG to parotitis virus	D-2602
20.	VectorParotitis-IgM	ELISA kit for determination of IgM to parotitis virus	D-2604
21.	Toxocara-IgG-EIA-BEST	ELISA kit for determination of IgG to toxocara antigens	D-2752
22.	Opisthorchiasis - IgG-EIA-BEST	ELISA kit for determination of IgG to opisthorchiasis antigens	D-2952
23.	Echinococcus-IgG-EIA-BEST	ELISA kit for determination of IgG to Echinococcus	D-3356

24.	Ascarid-IgG-EIA-BEST	antigens ELISA kit for determination of IgG to Ascaris lumbricoides	D-3452
25.	Lambliia-antibodies-EIA-BEST	ELISA kit for determination of IgG, IgM and IgA to Lambliia antibodies	D-3552
26.	Lambliia-IgM-EIA-BEST	ELISA kit for determination of IgM to Lambliia antibodies	D-3554
27.	Lambliia-antigen-EIA-BEST	ELISA kit for determination of Lambliia antigen	D-3558
28.	Helicobacter pylori-Caga-antigen-EIA-BEST	ELISA kit for determination of total antibodies to Caga Helicobacter pylori	D-3752
29.	TSH-EIA-BEST	ELISA kit for determination of concentration of thyroid-stimulating hormone	X-3952
30.	T3 total-EIA-BEST	ELISA kit for determination of concentration of total triiodothyronine	X-3954
31.	T4 total-EIA-BEST	ELISA kit for determination of concentration of total thyroxine	X-3956
32.	Anti-TPO-EIA-BEST	ELISA kit for determination of antibody concentration to thyroperoxidase	X-3968
33.	PAPP-A-EIA-BEST	ELISA kit for determination of concentration of pregnancy-associated plasma protein A	D-4160
34.	Mycoplasma hominis-IgG-EIA-BEST	ELISA kit for determination of IgG to Mycoplasma hominis	D-4352
35.	Mycoplasma hominis-IgA-EIA-BEST	ELISA kit for determination of IgA to Mycoplasma hominis	D-4358
36.	Mycoplasma pneumoniae-IgG-EIA-BEST	ELISA kit for determination of IgG to Mycoplasma pneumoniae	D-4362
37.	Mycoplasma pneumoniae-IgM-EIA-BEST	ELISA kit for determination of IgM to Mycoplasma pneumoniae	D-4366
38.	Vectocrimean - CHF - IgG	ELISA kit for determination of IgG to Crimean-Congo hemorrhagic fever virus	D-5052
39.	Vectocrimean - CHF - IgM	ELISA kit for determination of IgM to Crimean-Congo hemorrhagic fever virus	D-5054
40.	CEA-EIA-BEST	ELISA kit for determination of concentration of carcinoembryonic antigen	T-8454
41.	AFP-EIA-BEST	ELISA kit for determination of concentration of Alpha-Fetal Protein	T-8456
42.	CA-125-EIA-BEST	ELISA kit for determination of concentration of oncomarker CA-125	T-8466
43.	CA 19-9-EIA-BEST	ELISA kit for determination of concentration of CA 19-9	T-8470
44.	CA 15-3-EIA-BEST	ELISA kit for determination of concentration of oncomarker CA 15-3	T-8472
45.	NSE-EIA-BEST	ELISA kit for determination of concentration of neuron specific enolase	T-8476

46.	Ferritin-EIA-BEST	ELISA kit for determination of concentration of ferritin	T-8552
47.	IgE total-EIA-BEST	ELISA kit for determination of concentration of total IgE	A-8660
48.	IgG total-EIA-BEST	ELISA kit for determination of concentration of total IgG	A-8662
49.	IgM total-EIA-BEST	ELISA kit for determination of concentration of total IgM	A-8664
50.	IgA total-EIA-BEST	ELISA kit for determination of concentration of total IgA	A-8666
51.	Gamma-Interferon-EIA-BEST	ELISA kit for determination of concentration of gamma-interferon	A-8752
52.	Interleukine-4-EIA-BEST	ELISA kit for determination of concentration of Interleukine-4	A-8754
53.	Alpha-TNF-EIA-BEST	ELISA kit for determination of concentration of alpha-tumor necrosis factor	A-8756
54.	Alpha-Interferon-EIA-BEST	ELISA kit for determination of concentration of alpha-interferon	A-8758
55.	Interleukine-6-EIA-BEST	ELISA kit for determination of concentration of Interleukine-6	A-8768
56.	Interleukine-2-EIA-BEST	ELISA kit for determination of concentration of Interleukine-2	A-8772
57.	Procalcitonin-EIA-BEST	ELISA kit for determination of concentration of procalcitonin	A-9004
58.	NTproBNP-EIA-BEST	ELISA kit for determination of concentration of N-terminal prohormone of brain natriuretic peptide	A-9102
59.	Troponin I-EIA-BEST	ELISA kit for determination of concentration of troponin I	A-9106

GBG-MDL SRL
Global Biomarketing Group
Moldova
65 Tighina Str., office 607
MD-2001 Chisinau
Republic of Moldova

NovaTec Immundiagnostica GmbH
Waldstraße 23 A6
63128 Dietzenbach, Germany
Tel.: +49 (0) 60 74/4876-0
Fax: +49 (0) 60 74/4876-29
E-Mail: info@NovaTec-ID.com
Internet: www.NovaTec-ID.com

November 18th, 2019

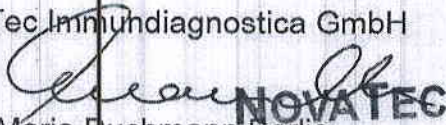
To whomever it may concern:

By hereby, we, **NovaTec Immundiagnostica GmbH**, Waldstraße 23 A6, 63128 Dietzenbach, Germany, declare that **GBG-MDL SRL** Global Biomarketing Group Moldova, 65 Tighina Str., office 607, MD-2001 Chisinau, Republic of Moldova is our authorized distributor designated by us to promote, to register, to distribute and to represent our products in the territory of the Republic of Moldova.

This declaration is valid until December 31th, 2020 unless terminated by either party before the date of expiration.

With best regards

NovaTec Immundiagnostica GmbH


NOVATEC
Britta-Maria Duchmann Berlie
General Manager IMMUNDIAGNOSTICA GmbH
Waldstraße 23 A6
63128 Dietzenbach, Germany

Product List – CE Marked

Certified by

ISO 13485:2016

EC – Directive 98 / 79/EC
For In-Vitro-Diagnostics

NovaLisa®

Virology

Prod. No.	Name
ADVA0010	Adenovirus IgA
ADVG0010	Adenovirus IgG
ADVM0010	Adenovirus IgM
CHM00599	Chikungunya Virus IgG-capture
CHM0590	Chikungunya Virus IgM µ-capture
CMVG0110	Cytomegalovirus (CMV) IgG
ACMV7110	Avidity Cytomegalovirus (CMV) IgG
CMVM0110	Cytomegalovirus (CMV) IgM
DENG0120	Dengue Virus IgG
DENM0120	Dengue Virus IgM
DVM0640	Dengue Virus IgM µ-capture
EBVA0150	Epstein-Barr Virus (VCA) IgA
EBVG0150	Epstein-Barr Virus (VCA) IgG
AEBV7150	Avidity Epstein-Barr Virus (VCA) IgG
EBVM0150	Epstein-Barr Virus (VCA) IgM
EBVG0580	Epstein-Barr Virus (EBNA) IgG
HANG0670	Hantavirus IgG
HANM0670	Hantavirus IgM
HEVG0780	Hepatitis E Virus (HEV) IgG
HEVM0780	Hepatitis E Virus (HEV) IgM
HSVG0250	Herpes simplex Virus 1+2 (HSV) IgG
HSV0250	Herpes simplex Virus 1+2 (HSV) IgM
HSV1G0500	Herpes simplex Virus 1 (HSV-1) IgG
HSV1M0500	Herpes simplex Virus 1 (HSV-1) IgM
HSV2G0540	Herpes simplex Virus 2 (HSV-2) IgG
HSV2M0540	Herpes simplex Virus 2 (HSV-2) IgM
INFA0290	Influenza Virus A IgA
INFG0290	Influenza Virus A IgG
INFM0290	Influenza Virus A IgM
INFA0300	Influenza Virus B IgA
INFG0300	Influenza Virus B IgG
INFM0300	Influenza Virus B IgM
MEAG0330	Measles Virus IgG
AMEA7330	Avidity Measles Virus IgG
MEAM0330	Measles Virus IgM
MUMG0340	Mumps Virus IgG
MUMM0340	Mumps Virus IgM
PAIA0360	Parainfluenza Virus 1,2,3 IgA
PAIG0360	Parainfluenza Virus 1,2,3 IgG
PARG0370	Parvovirus B 19 IgG
PARM0370	Parvovirus B 19 IgM
RSVA0380	Respiratory syncytial Virus IgA
RSVG0380	Respiratory syncytial Virus IgG
RSVM0380	Respiratory syncytial Virus IgM
RUBG0400	Rubella Virus IgG
ARUG7400	Avidity Rubella Virus IgG

2019-10

RUBM0400 Rubella Virus IgM µ-capture
TICG0440 TBE / FSME IgG
TICM0440 TBE / FSME IgM
PTICG044 TBE / FSME IgG plus

VZVA0490 Varicella-Zoster Virus (VZV) IgA
VZVG0490 Varicella-Zoster Virus (VZV) IgG
VZVM0490 Varicella-Zoster Virus (VZV) IgM
ZVG0790 Zika Virus IgG capture
ZVM0790 Zika Virus IgM µ-capture

NovoLisa® Bacteriology

Prod. No.	Name
BAR0900	Bartonella
BOPA0030	Bordetella pertussis IgA
BOPG0030	Bordetella pertussis IgG
BOPM0030	Bordetella pertussis IgM
BPTA0610	Bordetella pertussis toxin (PT) IgA
BPTG0610	Bordetella pertussis toxin (PT) IgG
BORG0040	Borrelia burgdorferi IgG
BORM0040	Borrelia burgdorferi IgM
BRUG0050	Brucella IgG
BRUM0050	Brucella IgM
CHLA0070	Chlamydia trachomatis IgA
CHLG0070	Chlamydia trachomatis IgG
CHLM0070	Chlamydia trachomatis IgM
CHLA0510	Chlamydia pneumoniae IgA
CHLG0510	Chlamydia pneumoniae IgG
CHLM0510	Chlamydia pneumoniae IgM
CORG0090	Corynebacterium diphtheriae toxin IgG
CORG5009	Corynebacterium diphtheriae toxin 5S IgG
PCORG009	Corynebacterium diphtheriae toxin 5S IgG plus
COX1G0600	Coxiella burnetii (Q-Fever) Phase 1 IgG
COX2G0600	Coxiella burnetii (Q-Fever) Phase 2 IgG
COX2M0600	Coxiella burnetii (Q-Fever) Phase 2 IgM
HELA0220	Helicobacter pylori IgA
HELG0220	Helicobacter pylori IgG
PHELA022	Helicobacter pylori IgA plus
PHELG022	Helicobacter pylori IgG plus
LEGG0650	Legionella Pneumophila IgG
LEGM0650	Legionella Pneumophila IgM
LEPG0660	Leptospira IgG
LEPM0660	Leptospira IgM
MYCA0350	Mycoplasma pneumoniae IgA

MYCG0350 Mycoplasma pneumoniae IgG
MYCM0350 Mycoplasma pneumoniae IgM
TETG0430 Clostridium tetani toxin IgG
TETG5043 Clostridium tetani toxin 5S IgG
PTETG043 Clostridium tetani toxin 5S IgG plus

NovoLisa® Parasites

Prod. No.	Name
CHAG0560	Chagas (Trypanosoma cruzi) IgG
TRYP0570	Chagas
ENTG0140	Entamoeba histolytica IgG
LEIG0310	Leishmania infantum IgG
MAL0620	Malaria
TOXA0460	Toxoplasma gondii IgA
TOXG0460	Toxoplasma gondii IgG
ATOX7460	Avidity Toxoplasma gondii IgG
TOXM0460	Toxoplasma gondii IgM µ-capture

NovoLisa® Worms

Prod. No.	Name
ASCG0020	Ascaris lumbricoides IgG
ECHG0130	Echinococcus IgG
FIL0760	Filariasis
SCHG0410	Schistosoma mansoni IgG
SCHM0410	Schistosoma mansoni IgM
STRO0690	Strongyloides
TAEG0420	Taenia solium IgG
TOCG0450	Toxocara canis IgG
TRIG0480	Trichinella spiralis IgG

NovoLisa® Fungi

Prod. No.	Name
ASPG0680	Aspergillus fumigatus IgG
ASPM0680	Aspergillus fumigatus IgM
CANA0060	Candida albicans IgA
CANG0060	Candida albicans IgG
CANM0060	Candida albicans IgM

GBG-MDL SRL
Global Biomarketing Group
Moldova
65 Tighina Str., office 607
MD-2001 Chisinau
Republic of Moldova

NovaTec Immundiagnostica GmbH
Waldstraße 23 A6
63128 Dietzenbach, Germany
Tel.: +49 (0) 60 74/4876-0
Fax: +49 (0) 60 74/4876-29
E-Mail: info@NovaTec-ID.com
Internet: www.NovaTec-ID.com

November 18th, 2019

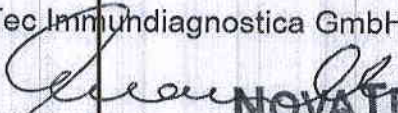
To whomever it may concern:

By hereby, we, **NovaTec Immundiagnostica GmbH**, Waldstraße 23 A6, 63128 Dietzenbach, Germany, declare that **GBG-MDL SRL** Global Biomarketing Group Moldova, 65 Tighina Str., office 607, MD-2001 Chisinau, Republic of Moldova is our authorized distributor designated by us to promote, to register, to distribute and to represent our products in the territory of the Republic of Moldova.

This declaration is valid until December 31th, 2020 unless terminated by either party before the date of expiration.

With best regards

NovaTec Immundiagnostica GmbH


NOVATEC
Britta-Maria Duchmann Berle
General Manager IMMUNDIAGNOSTICA GmbH
Waldstraße 23 A6
63128 Dietzenbach, Germany

Реагенты для определения группы крови человека, производимые ООО "Медиклон", зарегистрированы Минздравсоцразвития РФ и включены в Реестре препаратов, использование которых разрешено в больницах, станциях переливания крови и других лечебно-профилактических учреждениях без исключения.

Все планшеты, штативы, полиглюкин33% и ЦОЛИКЛОНЫ производимые ООО "Медиклон" не подлежат обязательной сертификации.

ООО "Медиклон" создано в 1999 г. и является одним из трех крупных Российских производителей полной панели реагентов для определения групповой принадлежности крови и резус-фактора –А,АI,Асл,В,АВ, Д,Е,С,е.с. и Келл.

Основной целью нашей работы является снабжение клиничко-диагностических лабораторий больниц и станций переливания крови реагентами для типирования групп крови и резус фактора,а также всеми необходимыми для этой работы расходными материалами. Для расфасовки реагентов нами в 1999 году впервые применены пластиковые флаконы-капельницы, что не только удобно для работы в лаборатории , но и исключает загрязнение реагентов, возможное при использовании пипеток. Теперь этому примеру последовали и другие Российские компании.

Качество наших реагентов является общепризнанным. Они имеют высокую активность и стабильность , что достигается тщательным внутреннем контролем и контролем со стороны уполномоченных организаций , в частности, Московской ГСПК.



МЕДИКЛОН

ООО "Медиклон"

127276-Москва, Ботаническая ул., 35. Т/ф +7495-231-2272 +7499-502-1214

П А С П О Р Т – С Е Р Т И Ф И К А Т П Р О И З В О Д И Т Е Л Я
на «Набор реагентов для определения групп крови человека систем
АВО, Резус и Келл» по ТУ-9398-101-51203590-2009
(ЦОЛИКЛОНЫ Анти-А, Анти-В и Анти-АВ)
Регистрационное удостоверение №ФСР 2009/06043 от 05 ноября 2009 г.

Наименование: Цоликлон Анти-А во флаконах по 10 мл с красными крышками

Серия: 096111

Единица: 100 мл

Изготовлен: 05.11.2019

Количество единиц: 40

Годен до: 05.11.2021

Объем серии: 10000 мл.

Паспорт: А096111 от 05.11.2019

Наименование показателя	Норма по ТУ	Результат испытания
1. Внешний вид		
1.1 Цоликлон анти-А	Прозрачная жидкость красного цвета.	Соответствует
1.2 Цоликлон анти-В	Прозрачная жидкость синего цвета.	
1.3 Цоликлон анти-АВ	Прозрачная бесцветная жидкость.	
2. Серологические свойства		
2.1 Специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп В(III) и O(I) Цоликлон анти-В не должен давать агглютинации с эритроцитами групп А(III) и O(I) Цоликлон анти-АВ не должен давать агглютинации с эритроцитами групп O(I)	Соответствует
2.2 Гемолитическая способность	Агглютиновая реакция эритроцитов А I и B с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует 10 секунд
2.3 Титр	Титр Цоликлона анти-А в реакции агглютинации на пасокости с эритроцитами группы A(III) 1:32 - 1:64 Титр Цоликлона анти-В в реакции агглютинации на пасокости с эритроцитами группы B(III) 1:64	Соответствует 1:64
	Титр Цоликлона анти-АВ в реакции агглютинации на пасокости с эритроцитами групп A(III) и B(III) 1:64	Соответствует 1:32 - 1:64

Цоликлон соответствует требованиям ТУ - 9398-101-51203590-2009



Заведующая ОТК ООО «Медиклон»

М.С. Орлова



ООО "Медиклон"

127276, Москва, Богородицкая ул., 35, 1-й ф. +7 495 231-2272 +7 499 502-1214

П А С П О Р Т – С Е Р Т И Ф И К А Т П Р О И З В О Д И Т Е Л Я
на «Набор реагентов для определения групп крови человека систем
ABO, Резус и Келл» по ТУ-9398-101-51203590-2009
(Ц О Л И К Л О Н Ы Анти-А, Анти-В и Анти-АВ)
Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-В во флаконах по 10 мл с синими крышками

Серия: 095810 Единица: 100 мл

Изготовлен: 21.10.2019 Количество единиц 40

Фолд-до: 21.10.2021 Объем серии: 10000-мл.

Паспорт: В095810 от 21.10.2019

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид		
1.1 Цоликлон анти-А	Прозрачная жидкость красного цвета.	Соответствует
1.2 Цоликлон анти-В	Прозрачная жидкость синего цвета.	
1.3 Цоликлон анти-АВ	Прозрачная бесцветная жидкость.	
2. Серологические свойства		
2.1 Специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп В(III) и O(I) Цоликлон анти-В не должен давать агглютинации с эритроцитами групп А(III) и O(I) Цоликлон анти-АВ не должен давать агглютинации с эритроцитами группы O(I) Агглютинация на плазмоскости эритроцитов А1 и В соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует Соответствует Соответствует Соответствует 10 секунд
2.2 Геммагглютинирующая способность	Тип Цоликлона анти-А в реакции агглютинации на плазмоскости с эритроцитами группы А(II) 1:32 - 1:64 Тип Цоликлона анти-В в реакции агглютинации на плазмоскости с эритроцитами группы В(III) 1:32 - 1:64	Соответствует 1:64
2.3 Тип	Тип Цоликлона анти-АВ в реакции агглютинации на плазмоскости с эритроцитами групп А(III) 1:32 - 1:64 и В(III) 1:64	Соответствует 1:32 - 1:64

Цоликлон соответствует требованиям ТУ-9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон»

М.С. Орлова





ООО "Медиклон"

127276-Москва, Ботаническая ул., 35 - АФ +7495-231-2272 +7499-502-1214

ПАСПОРТ – СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ
на «Набор реагентов для определения групп крови человека систем
АВО, Резус и Келл» по ТУ-9398-101-51203590-2009
(ЦОЛИКЛОНЫ Анти-А, Анти-В и Анти-АВ)
Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: ЦОЛИКЛОН Анти-АВ

Серия: 098611

Единица: 100 мл

Изготовлен: 05.11.2019

Количество единиц 10

Годен до: 05.11.2021

Объем серии: 10000 мл.

Паспорт: АВ098611 от 05.11.2019

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид		
1.1 Цоликлон анти-А	Прозрачная жидкость красного цвета.	Соответствует
1.2 Цоликлон анти-В	Прозрачная жидкость синего цвета.	
1.3 Цоликлон анти-АВ	Прозрачная бесцветная жидкость.	
2. Серологические свойства		
2.1 Специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп В(III) и O(I) Цоликлон анти-В не должен давать агглютинации с эритроцитами групп А(II) и O(I) Цоликлон анти-АВ не должен давать агглютинации с эритроцитами группы O(II) Агглютинация на глюкоэста-эритроцитов-А1 и-В с соответствующими Цоликлонами должна появляться не позднее 10 сек. после смешивания	Соответствует Соответствует Соответствует Соответствует 10 секунда
2.2 Гемагглютинирующая способность	Тип Цоликлона анти-А в реакции агглютинации на глюкоэста с эритроцитами группы А(II) 1:32 - 1:64 Тип Цоликлона анти-В в реакции агглютинации на глюкоэста с эритроцитами группы В(III) 1:64	Соответствует 1:32 - 1:64
2.3 Тип	1:64 Тип Цоликлона анти-АВ в реакции агглютинации на глюкоэста с эритроцитами групп А(II), В(III) и O(I) 1:64	Соответствует 1:32 - 1:64

Цоликлон соответствует требованиям ТУ - 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон»

М.С. Орлова



МЕДИКІОН

127276 Москва, Боготинская ул., 35. Т/ф (495) 231-2272 (499) 502-1214

ООО "Медикіон"

П А С П О Р Т – С Е Р Т И Ф И К А Т П РОИЗВОДИТЕЛЯ
на «Набор реагентов для определения групп крови человека систем
АВО, Резус и Келл» по ТУ-9398-101-51203590-2009

(ЦОЛИКІОН Анти-Д Сулер)
Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликіон Анти-Д Сулер во флаконах по 10 мл с зелеными крышками

Серия: 292711

Емкость: 100 мл

Изготовлен: 05.11.2019

Количество единиц: 40

Годен до: 05.11.2021

Объем серии: 10000 мл.

Паспорт: Дс292711 от 05.11.2019

Наименование показателя	Характеристика нормы по ТУ	Результаты испытаний
1. Внешний вид	Прозрачная жидкость светло-бежевого цвета	Соответствует
2. Серологические свойства		
2.1 Специфичность	Цоликіон Анти-Д Сулер не должен агглютинировать D(-) эритроциты.	Соответствует
2.2 Гематиптицирующая способность	Четкая реакция агглютинации должна наступить в течение 30 сек. после смешивания реагента с D(+)-эритроцитами.	Соответствует 30 сек.
2.3 Тип	Тип Цоликіона Анти-Д Сулер в реакции агглютинации на реактивности с D(+) эритроцитами 1:32 Тип Цоликіона Анти-Д Сулер в реакции прямой агглютинации с D(+) эритроцитами в микроплаке не ниже 1:256	Соответствует 1:32 1:256

Цоликіон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая ОТК ООО «Медикіон»

М.С.Орлова



ООО "Медиклон"

МЕДИКЛОН

127276 Москва, Ботаническая ул., 35, Г\Ф (495) 231-2272 (499) 502-1214

ПАСПОРТ-СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ
на набор реагентов для определения групп крови человека систем
ABO, Резус и Келл по ТУ-9398-101-51203590-2009

(ЦОЛИКЛОН Анти-D (D₅G))

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-D(D₅G)

Серия: 292110 Единица: 100 мл

Изготовлен: 28.10.2019 Количество единиц 10

Годен до: 28.10.2021 Объем серии: 10000 мл.

Паспорт: Дж292110 от 28.10.2019

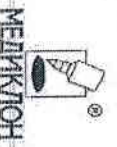
Наименование показателя	Характеристика нормы	Результаты испытаний
1. Внешний вид	Прозрачная жидкость светло-бежевого цвета	Соответствует
2. Серологические свойства		
2.1 Специфичность	Цоликлон Анти-D не должен агглютинировать D(-) эритроциты.	Соответствует
2.2 Гематогеннирующая способность	Агглютинация эритроцитов D+ с Цоликлоном в пробирочном тесте с желатином должна проявляться не позднее 15 мин.	Соответствует
2.3 Титр	Титр Цоликлона анти-D в пробирочном тесте с желатином 1:128. Титр Цоликлона в непрямом агглютинином тесте: 1:512	Соответствует

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон»

М.С. Орлова





ООО "Медиклон"

127276 Москва, Богачинская ул., 35, т/ф (495) 231-2272 (499) 502-1214

П А С П О Р Т - С Е Р Т И Ф И К А Т П Р О И З В О Д И Т Е Л Я
на набор реагентов для определения групп крови человека систем
ABO, Резус и Келл по ТУ-9398-101-51203590-2009

(ЦОМКАОН Анти-Келл Супер)

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликсон Анти-Келл Супер

Серия: 196410

Единица: 100 мл

Изготовлен: 21.10.2019

Количество единиц 10

Годен до: 21.10.2021

Объем серии: 10000 мл

Паспорт: К196410 от 21.10.2019

Наименование показателя	Характеристика нормы по ТУ	Результаты испытаний
1. Внешний вид	Прозрачная желтоватая или розоватая жидкость	Соответствует
2. Серологические свойства		
2.1 Специфичность	Положительная реакция агглютинировать эритроциты К(-) Четкая реакция агглютинации на плоскости должна наступать в течение 30 сек. после смешивания	Соответствует
2.2 Тематизмирующая способнось		Соответствует
2.2 Активность	Титр Цоликсона Анти-Келл Супер в реакции прямой агглютинации в микроцитате не ниже 1:16	Соответствует 1:16

Цоликсон соответствует требованиям ТУ – 9398-101-51203590-2009
Заведующая ОТК ООО «Медиклон»

М.С. Орлова