

Certificate

mdc medical device certification GmbH
certifies that

VECTOR



AO Vector-Best

Research and Production area
building 36, Office 211, Koltsovo
630559 Novosibirsk region
Russian Federation

with the locations listed in the attachment

for the scope

Design and development, production and distribution of
medical devices for in vitro diagnostics (PCR, ELISA, Biochemistry)
has introduced and applies a

Quality Management System

The mdc audit has proven that the quality management system
meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory control

EN ISO 13485:2016

mdc
Medical Device Certification
Research and Production
Building 36, Office 211, Koltsovo
630559 Novosibirsk region
Russian Federation

Head of Certification Body

mdc

(DAKKS)

Attachment of the certificate

No. D1213100017

date 2018-07-13

Page 1 of 1

Location	Scope
AO Vector-Best Abuzova str. 1/1 630117 Novosibirsk, Russian Federation	design and development, production and distribution of medical devices for in vitro diagnostics
AO Vector-Best Research and Production area, Building 36, Koltsovo, 630559 Novosibirsk region, Russian Federation	design and development, production of medical devices for in vitro diagnostics
AO Vector-Best, Pasechnaya str. 3, 630117 Novosibirsk, Russian Federation	design and development, production of medical devices for in vitro diagnostics

mdc

mdc Certification Body

EC DECLARATION OF CONFORMITY

Rev. 01	AO Vector-Best	
Page 1 of 3	EC Declaration of conformity HIA-1-17	

AO Vector-Best hereby ensures under own responsibility and declares that the products listed on pages 2-3 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)

Harmonized standards applied:

EN ISO 18113-1:2011; EN ISO 18113-2:2011 (In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Terms, definitions and general requirements. In vitro diagnostic reagents for professional use); EN ISO 15223-1:2012 (Symbols to be used with medical device labels, labelling and information to be supplied); EN ISO 13485:2012+AC:2012 (Medical devices. Quality management systems. Requirements for regulatory purposes); EN 15612:2002 (Performance evaluation of in vitro diagnostic medical devices); EN 23640:2013 (In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents); EN 13641:2002 (Elimination or reduction of risk of infection related to in vitro diagnostic reagents); EN ISO 14971:2012 (Medical devices. Application of risk management to medical devices).

Conformity assessment procedure:

Annex III (not including section 6).

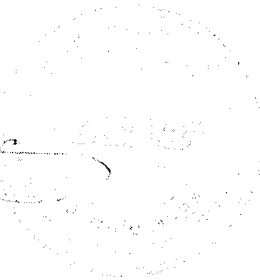
Manufacturer:

AO Vector-Best
Address: 630559, Koltsovo, Novosibirsk Region, Research and Production area, building 36, office 211, Russian Federation, tel. +7 (383) 336-73-46, tel./fax +7 (383) 332-67-49

European authorized representative:

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

Date: 2017/10/16

Murat Khusainov
General Director AO Vector-Best

Valid until: 2022/07/03

No.	Product name	Identification data	REF
1.	Vectonep A-IgG	Enzyme immunoassay kit for the qualitative and quantitative determination of IgG to hepatitis A virus.	D-0362
2.	Vectomeasles-IgG	Enzyme immunoassay kit for the qualitative and quantitative determination of IgG to measles virus in blood serum (plasma).	D-1356
3.	Vectomeasles-IgM	Enzyme immunoassay kit for the detection of IgM to measles virus in blood serum (plasma).	D-1358
4.	Rotavirus-antigen-EIA-BEST	Enzyme immunoassay kit for the detection of human rotavirus antigen.	D-1652
5.	Adenovirus antigen-EIA-BEST	Enzyme immunoassay kit for the detection of human adenovirus antigen.	D-1654
6.	VectoeBV-NA-IgG	Enzyme immunoassay kit for the detection of IgG to nuclear antigen of Epstein-Barr virus in blood serum (plasma).	D-2170
7.	VectoeBV-EA-IgG	Enzyme immunoassay kit for the detection of IgG to early antigens of Epstein-Barr virus in blood serum (plasma).	D-2172
8.	VectoeBV-VCA-IgM	Enzyme immunoassay kit for the detection of IgM to viral capsid antigen of Epstein-Barr virus in blood serum (plasma).	D-2176
9.	VectoMumps-IgG	Enzyme immunoassay kit for the detection of IgG to mumps virus in blood serum (plasma).	D-2602
10.	VectoMumps-IgM	Enzyme immunoassay kit for the detection of IgM to mumps virus in blood serum (plasma).	D-2604
11.	Toxocara-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to Toxocara antigens in blood serum (plasma).	D-2752
12.	Trichinella-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to Trichinella antigens in blood serum (plasma).	D-3152
13.	Yersinia-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to causative agents of yersiniosis.	D-3202
14.	Yersinia-IgA-EIA-BEST	Enzyme immunoassay kit for the detection of IgA to causative agents of yersiniosis.	D-3204
15.	Yersinia-IgM EIA-BEST	Enzyme immunoassay kit for the detection of IgM to causative agents of yersiniosis.	D-3206
16.	Echinococcus-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to Echinococcus granulosus antigens in blood serum (plasma).	D-3356
17.	Ascaris-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to Ascaris lumbricoides antigens in blood serum (plasma).	D-3452
18.	IgA-Transglutaminase-EIA-BEST	Enzyme immunoassay kit for the quantitative determination of IgA to tissue transglutaminase in blood serum (plasma).	D-3758
19.	IgG-Transglutaminase-EIA-BEST	Enzyme immunoassay kit for the quantitative determination of IgG to tissue transglutaminase in blood serum (plasma).	D-3760
20.	Pepsinogen 1-EIA-BEST	Enzyme immunoassay kit for the determination of pepsinogen concentration in blood serum.	D-3762
21.	Pepsinogen 2 EIA-BEST	Enzyme immunoassay kit for the determination of pepsinogen concentration in blood serum.	D-3764

22.	VectoHanta-IgG	Enzyme immunoassay kit for the detection of IgG to Hantavirus in blood serum (plasma).	D-4902
23.	VectoHanta-IgM	Enzyme immunoassay kit for the detection of IgM to Hantavirus in blood serum (plasma).	D-4904
24.	VectoNile-IgM	Enzyme immunoassay kit for the detection of IgM to West Nile Virus in blood serum (plasma).	D-5150
25.	VectoNile-IgG	Enzyme immunoassay kit for the detection of IgG to West Nile Virus in blood serum (plasma).	D-5152
26.	VectoNile-IgG-avidity	Enzyme immunoassay kit for the determination of avidity index of IgG to West Nile Virus in blood serum (plasma).	D-5154



EC DECLARATION OF CONFORMITY

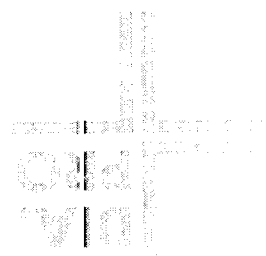
MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 - 20099 SESTO SAN GIOVANNI (MILANO) - ITALY
PRODUCT	CMV IgG CODE: CMVG.CE (96 tests)
CLASSIFICATION	ANNEX II - LIST B ANNEX IV
CONFORMITY ASSESSMENT ROUTE	

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)	• 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 • UNITED 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) MAY 2018
SIGNATURE	Legal Representative Dr.ssa Fiorenza Scozzesi

Rev. 01/2018



EC DECLARATION OF CONFORMITY

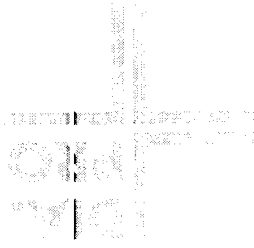
MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 - 20099 SESTO SAN GIOVANNI (MILANO) - ITALY
PRODUCT	CMV IgM CODE: CMV.M.CE (96 tests)
CLASSIFICATION	ANNEX II - LIST B ANNEX IV
CONFORMITY ASSESSMENT ROUTE	

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PRODUCT MEETS THE PROVISIONS OF THE COUNCIL
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PLACE & DATE OF FIRST ISSUE	MILANO - MAY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) - MAY 2018
SIGNATURE	Dr.ssa Fiorenza Scozzesi Legal Representative

RCA 05/2018



EC DECLARATION OF CONFORMITY

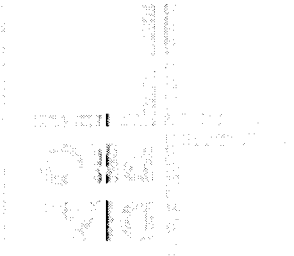
MANUFACTURER		DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 - 20099 SESTO SAN GIOVANNI (MILANO) - ITALY
PRODUCT		HSV1&2 IgG CODE: HSVG.CE (96 tests)
CLASSIFICATION		GENERAL IVD
CONFORMITY ASSESSMENT ROUTE		SELF CERTIFICATION

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		UNE EN ISO 13485 N° 2013 11 0039 EN. RELEASSED BY AEMPS (AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANTARIOS)
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PLACE & DATE OF FIRST ISSUE		MILANO - MARCH 2004
PLACE & DATE OF CURRENT ISSUE		SESTO SAN GIOVANNI (MI) - MARCH 2019
SIGNATURE		Legal Representative Drs.ssa Fiorenza Scozzesi

Rev. 05/2018



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: HSVM.CF (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	UNE EN ISO 13485 N° 2013 11 0039 EN. RELEASED BY AIMPS (AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS)
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PLACE & DATE OF FIRST ISSUE	MILANO - OCTOBER 2004
PLACE & DATE OF CURRENT ISSUE	SESTO SAN GIOVANNI (MI) - MARCH 2019
SIGNATURE Legal Representative Drs.ssa Fiorenza Scozzesi	

Rev: 01/2018



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 IgA CODE: HPA.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.

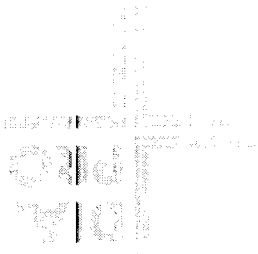
ISO CERTIFICATE	UNE EN ISO 13485 N° 2013 11 0039 EN. RELEASED BY AEMPS (AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS)
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PLACE & DATE OF FIRST ISSUE	MILANO - MARCH 2004
PLACE & DATE OF CURRENT ISSUE	SESTO SAN GIOVANNI (MI) - MARCH 2019
SIGNATURE	Legal Representative Dr.ssa Fiorenza Scozzesi

Rev: 03/2018

EC DECLARATION OF CONFORMITY

Dia.Pro
Diagnostic
 Bio**Pro**bes



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

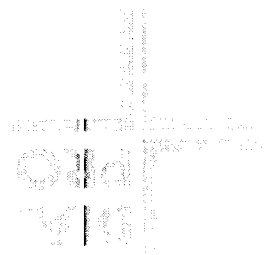
WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS
 THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC
 FOR IN VITRO DIAGNOSTIC DEVICES.

ISO CERTIFICATE	UNE EN ISO 13485 N° 2013 11 0039 EN. RELEASED BY AEMPS (AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS)
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PLACE & DATE OF FIRST ISSUE	MILANO – MARCH 2004
PLACE & DATE OF CURRENT ISSUE	SESTO SAN GIOVANNI (MI) – MARCH 2019
SIGNATURE Legal Representative Drs.ssa Fiorenza Scozzesi	

Rev. 05/2018

DIA.PRO Diagnostic Bioprobes S.r.l.
 Sede legale e lab.: Via G. Carducci, 27 – 20099 Sesto S. Giovanni (MI) – Italia
 Tel. +39 02 2700716/6450 • Fax +39 02 44386771 • <http://www.diapro.it> • E-mail: info@diapro.it
 Capitale sociale €50.000,00 I.V. – P.IVA: 11924660159 – Reg. Imp. 11924660159 – REA 1509959



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 ANNEX IV
CONFORMITY ASSESSMENT ROUTE	

WE HEREBY DECLARE THAT THE ABOVE MENTIONED
PRODUCT MEETS THE PROVISIONS OF THE COUNCIL
DIRECTIVE 98/79/EC
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NOTIFIED BODY (EC) CERTIFICATE(S)	AEMPS - n° 0318 • 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 • UNITED 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) - MAY 2018
SIGNATURE Legal Representative Drs.ssa Fiorenza Scozzesi	

Rev. 05/2018

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 - 20099 SESTO SAN GIOVANNI (MI) - 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
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NOTIFIED BODY	AEMPS - n° 0318
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PLACE & DATE OF FIRST ISSUE	MILANO - MAY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) - MAY 2018
SIGNATURE Legal Representative Drs.ssa Fiorenza Scozzesi	

Rev 05 2018

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: ESPOOR/LAAN 13, 3951DB MAARN, THE NETHERLANDS.
(on product labels printed as:
CEpartner4U, ESPOOR/LAAN 13, 3951DB MAARN, THE NETHERLANDS Tel: +31 (0)6 516 536 26,
or as: CEpartner4U, 3951DB 13 NL tel: +31 (0)6 - 516 536 26)

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

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

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

Document No. **Title** **Edition / Date of issue**
L 331: 98/79/EC **In-Vitro-Diagnostic Directive** **1998-10-27**

5) Additional information (conformity procedure, Notified Body, CE certificate, etc.):
Conformity assessment procedure for CE marking, IVD Directive, Annex III

Lake Forest, USA, 2011-09-27

Tony Sharda, QA Director, Monobind Inc.
(Place & date of issue (yyyy-mm-dd)) (Name, function and signature of manufacturer)

Maarn, NL, 2011-09-27

Oliga Ierlinck, Consultant, CEpartner4U BV
(Place & date of issue (yyyy-mm-dd)) (Name, function and signature of authorized representative)

Appendix

Date: 2011-09-26

Device types	Item# ELISA	Item# CLIA	Item# Control	Item# Instrument	EDMS code	Risk Class	Certificate #	First date of CE marking
Thyroid								
T3 - Triiodothyronine	1225-300	1775-300			12 04 01 05 00	Low		2005-11-11
T3 - Free Triiodothyronine	1225-300	1375-300			12 04 01 01 00	Low		2005-11-11
T4 - Thyroxine	2225-300	275-300			12 04 01 07 00	Low		2005-11-11
T4 - Free Thyroxine	1225-300	1275-300			12 04 01 02 00	Low		2005-11-11
TSH - Thyrotropin	325-300	375-300			12 04 01 11 00	Low		2005-11-11
Rapid TSH - Rapid Thyrotropin	6025-300	6075-300			12 04 01 06 00	Low		2010-06-29
T3U - Triiodothyronine Uptake	525-300	575-300			12 04 01 09 00	Low		2005-11-11
T4U - Thyroxine Binding Globulin	3525-300	3575-300			12 04 01 08 00	Low		2005-11-11
T3 - Thyroglobulin	2225-300	2275-300			12 04 01 09 00	Low		2005-11-11
T3 T4 & TSH - Triiodothyronine, Thyroxine & Thyrotropin Combo (VASI)	8025-300	8075-300			12 04 01 01 00	Low		2005-11-11
T3 - Triiodothyronine (SBS)	8125-300	8175-300			12 04 01 01 00	Low		2010-06-29
T4 - Thyroxine (SBS)	8225-300	8275-300			12 04 01 01 00	Low		2010-06-29
T3 T4 & TSH - Free Triiodothyronine, Free Thyroxine & Thyrotropin Combo (VASI)	7025-300	7075-300			12 04 01 01 00	Low		2010-06-29
Neonatal Thyroid & Genetics								
TSH - Neonatal Thyrotropin	3425-300	3475-300			12 04 01 04 00	Low		2005-11-11
T4 - Neonatal Thyroxine	2625-300	2675-300			12 04 01 12 00	Low		2005-11-11
N 17OH - Neonatal 17-OH Progesterone	5525-300				12 05 01 07	Low		2008-02-01
Biotinidase	8825-300				12 07 02 00 00	Low		2011-06-26
Autoimmune Thyroid								
Anti-Tg - Anti-Thyroglobulin Antibody	1025-300	1075-300			12 10 03 04 00	Low		2005-11-11
Anti-TPO - Anti-Thyroid Peroxidase Antibody	1125-300	1175-300			12 10 03 01 00	Low		2005-11-11
Fertility & Prenatal								
LH - Luteinizing Hormone	625-300	675-300			12 05 01 05 00	Low		2005-11-11
FSH - Follicle Stimulating Hormone	425-300	475-300			12 05 01 04 00	Low		2005-11-11
PRL - Prolactin	725-300	775-300			12 05 01 06 00	Low		2005-11-11
PRL - Prolactin Subunit	6025-300	6075-300			12 05 01 08 00	Low		2005-11-11
hCG - Human Chorionic Gonadotropin	825-300	875-300			12 05 02 05 00	Low		2005-11-11
Rapid hCG - Rapid Human Chorionic Gonadotropin	3325-300				12 05 02 06 00	Low		2005-11-11
hCG - Human Chorionic Gonadotropin	8325-300	8375-300			12 05 01 90 00	Low		2006-09-24
AFP - Alpha Fetal Protein	8525-300	8575-300			12 05 01 90 00	Low		2010-06-29
Steroid								
Cortisol	3075-300	3075-300			12 06 02 04 00	Low		2005-11-11
Testosterone	5725-300	5775-300			12 06 01 02 00	Low		2010-06-29
Testosterone	4425-300	4475-300			12 06 01 02 00	Low		2011-06-26

Device Types	Item#	Item#	Item#	Item#	EDM's code	Risk Class	Certificate #	First date of
ELISA	CLIA	Control	Instrument					GE-marking
E2 - Estradiol	4925-300	4975-300			12 05 01 03 00	Low		2010-06-29
E2 - Estradiol (Unconjugated)	4925-300	4975-300			12 05 02 03 00	Low		2010-06-29
Progesterone	4825-300	4875-300			12 05 01 06 00	Low		2010-06-29
Testosterone	3725-300	3775-300			12 05 01 10 00	Low		2007-11-01
Free Testosterone	5325-300	5375-300			12 05 01 10 00	Low		2010-06-29
17OH-P - 17-Hydroxyprogesterone	5225-300	5275-300			12 05 01 07 00	Low		2010-06-29
17OH-P - 17-Hydroxyprogesterone	9925-300	9975-300			12 05 01 07 00	Low		2010-10-18
Ex: Range	7725-300	7775-300			12 06 03 10 00	Low		2011-09-26
Vitamin D3 - 25-Hydroxyvitamin D3								
Growth & Bone Metabolism								
PTH - Parathyroid Hormone	1725-300	1775-300			12 06 04 02 00	Low		2006-11-11
PTH - Parathyroid Hormone	7825-300	7875-300			12 06 03 13 00	Low		2011-09-26
Diabetes								
Insulin	2425-300	2475-300			12 06 01 03 00	Low		2006-11-11
Insulin Rapid	5625-300				12 06 01 03 00	Low		2010-06-29
C-peptide	2725-300	2775-300			12 06 01 01 00	Low		2006-11-11
Insulin & C-peptide Combo (VASI)	7325-300	7375-300			12 06 01 03 00	Low		2006-11-11
Cardiac Markers								
CK-MB - Circulating Creatine Kinase (MB)	2925-300	2975-300			12 13 01 02 00	Low		2006-11-11
CTnI - Troponin I	3825-300	3875-300			12 13 01 07 00	Low		2006-11-11
DTG - D-Dimer	925-300	975-300			12 08 01 01 00	Low		2006-11-11
HS-CRP - High Sensitivity C-Reactive Protein	3125-300	3175-300			12 13 01 06 00	Low		2006-11-11
Myoglobin	3225-300	3275-300			12 13 01 05 00	Low		2006-11-11
Infectious Diseases								
IG - AntiH Pylori	1425-300	1475-300			15 01 04 03 00	Low		2006-11-11
IGM - AntiH Pylori	1525-300	1575-300			15 01 04 03 00	Low		2006-11-11
IGA - AntiH Pylori	1625-300	1675-300			15 01 04 03 00	Low		2006-11-11
Cancer Markers								
AbT - Alpha-fetoprotein	1925-300	1975-300			12 03 06 01 00	Low		2006-11-11
CA-125 Ovarian Cancer Antigen	3025-300	3075-300			12 03 01 06 00	Low		2006-11-11
CA-19-9 Breast Cancer Antigen	5625-300	5675-300			12 03 01 02 00	Low		2010-06-29
CA-19-9 Pancreatic Cancer Antigen	3925-300	3975-300			12 03 01 03 00	Low		2006-11-11
CEA - Carcinoembryonic Antigen	8425-300	1875-300			12 03 01 31 00	Low		2010-06-29
CEA - Carcinoembryonic Antigen Next Generation	4625-300	4675-300			12 03 01 31 00	Low		2010-06-29
hCG - Free Beta Human Chorionic Gonadotropin	2025-300	2075-300			12 03 01 30 00	Low		2006-11-11
Allergy & Anemia								
E-erythrocyte	2875-300	2875-300			12 07 01 02 00	Low		2010-06-29
Erythrocyte	2975-300	2975-300			12 07 01 03 00	Low		2010-06-29
haptoglobin E	7475-300	7475-300			12 02 01 02 00	Low		2010-06-29
haptoglobin Soluble Receptor	8675-300	8675-300			12 07 01 06 00	Low		2010-06-29
Vitamin B12	7675-300	7675-300			12 07 02 04 00	Low		2010-06-29

Miscellaneous Controls							
Anti-IG & Anti-TPD - Positive & Negative - Anti-Thyroglobulin, Anti-Thyroxinase	AIT 101	12 50 01 16 00	Low				2010-06-29
High Level Fertility Control - Single Level - Progesterone, Estradiol	FC 300	12 50 01 16 00	Low				2010-06-29
Human Chorionic Gonadotropin	MC 300	12 50 01 16 00	Low				2010-06-29
Maternal Control - Tri Level - Human Chorionic Gonadotropin, Free Beta Human Chorionic Gonadotropin Subunit, Alpha Fetal Protein, Estradiol	TG-300	12 50 01 16 00	Low				2010-06-29
Thyroglobulin Control - Tri Level	THY-IG-300	12 50 01 16 00	Low				2010-06-29
h Pyridoxal Control - Positive & Negative							
Miscellaneous Instruments							
IC hardware + dedicated accessories + software - AutoFlex ELISA Analyser & Data Processor	IN006	21 02 10 01	Low				2010-06-29
IC hardware + dedicated accessories + software - Lumax Chemiluminescence Strip Reader	IN001	21 02 10 01	Low				2006-08-24
IC hardware + dedicated accessories + software - Non Lumax Chemiluminescence Strip Reader	IN010	21 02 10 01	Low				2011-09-26
IC hardware + dedicated accessories + software - Immulux 2 Chemiluminescence Strip Reader	IN005	21 02 10 01	Low				2010-06-29
IC hardware + dedicated accessories + software - Immulux 3 Chemiluminescence Strip Reader	IN007	21 02 10 01	Low				2010-06-29
IC hardware + dedicated accessories + software - Lumax56 Chemiluminescence Plate Reader	IN004	21 02 10 01	Low				2007-03-01
IC hardware + dedicated accessories + software - Lumax Chemiluminescence Plate Reader	IN008	21 02 10 01	Low				2011-09-26
IC hardware + dedicated accessories + software - Elysia 3.8 ELISA Strip Reader	IN003	21 02 10 01	Low				2007-09-10
IC hardware + dedicated accessories + software - Non Elysia ELISA Strip Reader	IN005	21 02 10 01	Low				2011-09-26
IC hardware + dedicated accessories + software - Microplate Washer	IN002	21 02 10 01	Low				2010-06-29



Certificate of Registration

of Quality Management System

to I.S. EN ISO 13485:2012

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

For the purpose of this certificate, the scope of the registration is limited to the following activities:

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



Annex to Certificate Number: MD19.4585

Scope of Registration:

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

Activity

Location

Headquarters, Design,
Manufacture

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

Manufacture, Design

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)

Approved by:
Geraldine Larkin
Chief Executive Officer

Approved by:
Susan Murphy
European Medical Device
Operations Manager

Registration Number: V 134585
Certification Granted: May 18, 2010
Effective Date: Oct 29, 2017
Expiry Date: Oct 28, 2020



**Verified by:
Operations Manager**

DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION

Product name	TPHA Microtitre plate kit
Catalogue number	043100A

MANUFACTURER

Name	Lorne Laboratories
Address	Unit 1 Cutbush Park Industrial Estate Danehill Lower Earley Berks, RG6 4UT
Country	United Kingdom

MEANS OF CONFORMITY

I hereby declare that the products listed above comply 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).

This declaration is valid from 17 May 2015.



Eddy Velhuis

Technical Director

DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION

Product name	RPR Carbon kit
Catalogue number	044150A 044500A

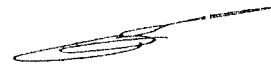
MANUFACTURER

Name	Lorne Laboratories
Address	Unit 1 Cutbush Park Industrial Estate Danehill Lower Earley Berks RG6 4UT United Kingdom
Country	United Kingdom

MEANS OF CONFORMITY

I hereby declare that the products listed above comply 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).

This declaration is valid from 17 May 2015.



Eddy Velthuis
Technical Director



Product List – CE Marked

Certified by

ISO 13485:2012

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

2018-02

440.2718.70

Novalisa® Prod. No	Virology Name
ADVA0010	Adenovirus IgA
ADVG0010	Adenovirus IgG
ADVM0010	Adenovirus IgM
CHIG0590	Chikungunya Virus IgG capture
CHIM0590	Chikungunya Virus IgM µ-capture
CYMG0110	Cytomegalovirus (CMV) IgG
ACV17110	Avidity Cytomegalovirus (CMV) IgG
CMV10110	Cytomegalovirus (CMV) IgM
DENG0120	Dengue Virus IgG
DENM0120	Dengue Virus IgM
CYM0640	Dengue Virus IgM µ-capture
EBVA0150	Epstein-Barr Virus (VCA) IgA
EBVG0150	Epstein-Barr Virus (VCA) IgG
AEBV7150	Avidity Epstein-Barr Virus (VCA) IgG
EBVA0150	Epstein-Barr Virus (VCA) IgM
EBV10480	Epstein-Barr Virus (EBNA) IgG
HAAG0510	Hantavirus IgG
HAAY0510	Hantavirus IgM
--SV02450	Herpes simplex Virus 1+2 (HSV) IgG
--SVV02450	Herpes simplex Virus 1+2 (HSV) IgM
--SV151000	Herpes simplex Virus 1 (HSV-1) IgG
--SV1V0430	Herpes simplex Virus 1 (HSV-1) IgM
--SV1000140	Herpes simplex Virus 2 (HSV-2) IgG
--SV2V0040	Herpes simplex Virus 2 (HSV-2) IgM
INAV0140	Influenza Virus A IgA
INFG0140	Influenza Virus A IgG
INVA0140	Influenza Virus A IgM
INBV0140	Influenza Virus B IgA
INBO0140	Influenza Virus B IgG
INVB0140	Influenza Virus B IgM
MEASV0140	Measles Virus IgG
--MV0140	Avidity Measles Virus IgG
MEASV0140	Measles Virus IgM
MMV0140	Mumps Virus IgG
MMV1140	Mumps Virus IgM
PARIF0140	Parainfluenza Virus 1,2,3 IgA
PARIF0140	Parainfluenza Virus 1,2,3 IgG
PARIV0140	Parvovirus B 19 IgG
PARIV0140	Parvovirus B 19 IgM
RSYNV0140	Respiratory syncytial Virus IgA
RSYNV0140	Respiratory syncytial Virus IgG
RSYNV0140	Respiratory syncytial Virus IgM
RUBEL0140	Rubella Virus IgG
AVIR0140	Avidity Rubella Virus IgG

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

Novalisa® Bacteriology

Prod. No.	Name
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	Bruceella IgG
BRUM0050	Bruceella 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
CORG009	Corynebacterium diphtheriae toxin IgS plus
PCORG009	Corynebacterium diphtheriae toxin IgS plus
COX1G0600	Coxiella burnetii (Q-Fever) Phase I IgG
COX2G0600	Coxiella burnetii (Q-Fever) Phase II IgG
COX2M0600	Coxiella burnetii (Q-Fever) Phase II IgM
HEL A0220	Helicobacter pylori IgA
HEL G0220	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
VVCA0350	Mycoplasma pneumoniae IgA
VVCG0350	Mycoplasma pneumoniae IgG
VVCM0350	Mycoplasma pneumoniae IgM

TETG0430 Clostridium tetani toxin IgG
TETG0403 Clostridium tetani toxin 5S IgG
PTETG043 Clostridium tetani toxin 5S IgG plus

Novalisa® Parasites

Prod. No.	Name
CHAG0560	Chagas (Trypanosoma cruzi) IgG
TRYP0570	Chagas
ENTG0140	Entamoeba histolytica IgG
GIA0160S	Giardia lamblia antigen
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

Novalisa® Worms

Prod. No.	Name
ASCG0020	Ascaris lumbricoides IgG
ECHG0130	Echinococcus IgG
FIL0760	Filariasis
SCHG0410	Schistosoma mansoni IgG
SCHM0410	Schistosoma mansoni IgM
SITRO0690	Strongyloides
TAEIG0420	Taenia solium IgG
TCEG0450	Toxocara canis IgG
TRIG0480	Trichinella spiralis IgG

Novalisa® Fungi

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

Novalisa[®] Hormones

THYROID HORMONES
(ELISAs for the determination of thyroid hormones and antibodies)

Prod. No.	Name
ATG1010	Anti-TG
ATPO1020	Anti-TPO
TSH1030	TSH

Novaline

Prod. No.	Name
TRYG2570	Chagas IgG Linebiot

Hormones

STERIOD HORMONES
(ELISAs for the determination of steroid hormones in plasma and serum)

Prod. No.	Name
DNOV001	Cortisol
DNOV002	Testosterone
DNOV003	17 beta Estradiol
DNOV004	17-OH Progesterone
DNOV005	DHEA-S
DNOV006	Progesterone
DNOV007	Free Estradiol
DNOV008	Androstenedione
DNOV009	Free Testosterone
DNOV011	Total Estradiol
DNOV012	Androstene

STERIOD HORMONES IN URINE
(ELISAs for the determination of steroid hormones in urine)

Prod. No.	Name
DNOV010	Cortisol (U/S)

STERIOD HORMONES IN SALIVA
(ELISAs for the determination of steroid hormones in saliva)

Prod. No.	Name
DSNOV20	Cortisol
DSNOV21	Testosterone
DSNOV22	Androstenedione

DSNOV24	DHEA-S Saliva
DSNOV25	Progesterone Saliva
DSNOV26	Estriol Saliva
DSNOV27	Androstenedione Saliva

PROTEIN HORMONES
(ELISAs for the determination of proteins in plasma and serum)

Prod. No.	Name
DNOV030	LH
DNOV031	FSH
DNOV032	Prolactin
DNOV033	AFP
DNOV034	beta HCG

THYROID HORMONES
(ELISAs for the determination of thyroid hormones and antibodies)

Prod. No.	Name
DNOV051	Free T3
DNOV052	Free T4
DNOV053	Total T3
DNOV054	Total T4
DNOV057	Thyroglobulin

DIABETES MONITORING
(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
DNOV111	Insulin
DNOV112	C-Peptide

CIRCULATING IMMUNO COMPLEXES
(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
DNOV093	C-ICK T3
DNOV094	C-ICK T4
DNOV096	C-ICK IgG

TUMOR MARKERS
(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
DNOV060	CEA
DNOV061	CA 15-3
DNOV062	CA 125

DNOV063 CA 19-9

MISCELLANEOUS
(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
DNOV100	Ferritin
DNOV101	HCG
DNOV102	IgE

Novalisa® Autoimmune

Autoimmune
(ELISAs for the determination of specific autoimmune antibodies)

Prod. No.	Name
ATG1010	Anti-TG
ATPO1020	Anti-TPO

Rheumatology
(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
RFW3910	Rheumatoid Factor IgM

Novalisa® Recombinant Antigens

Prod. No.	Name
BORG0040	Borrelia burgdorferi IgG
BORG0040	Borrelia burgdorferi IgM
CHAS0550	Cragas (Trypanosoma cruzi) IgG
TRV40570	Cragas
HAN30670	Hantavirus IgG
HANV0670	Hantavirus IgM
HE1A0200	Helicobacter pylori IgA
HE1A0210	Helicobacter pylori IgA plus
HSV1G0500	Herpes simplex Virus 1 (HSV-1) IgG
HSV1V0500	Herpes simplex Virus 1 (HSV-1) IgM
HSV2G040	Herpes simplex Virus 2 (HSV-2) IgG
HSV2V0540	Herpes simplex Virus 2 (HSV-2) IgM
VAG10010	VZV IgA
STRV0010	Streptococcus
STRV0010	Streptococcus pallidum
TRV10010	Trka Virus IgG capture

Novatec Immundiagnostica GmbH, 34109 Krefeld, Germany

ZVM0790 Zika Virus IgM µ-capture

Novalisa® Quantitative Assays (WHO standardized)

Prod. No.	Name
BPTA0610	Bordetella pertussis toxin (PT) IgA
BPTG0610	Bordetella pertussis toxin (PT) IgG
CORG0090	Corynebacterium diphtheriae toxin IgG
CORG0090	Corynebacterium diphtheriae toxin 5S IgG
PCORG009	Corynebacterium diphtheriae toxin 5S IgG plus
RFM3010	Rheumatoid Factor IgM
RUBG0400	Rubella Virus IgG
TETG0430	Clostridium tetani toxin IgG
TE1G5043	Clostridium tetani toxin 5S IgG
PTETG043	Clostridium tetani toxin 5S IgG plus
TOXG0460	Toxoplasma gondii IgG
ATOX7460	Avdity Toxoplasma gondii IgG
TSH1030	TSH

Novalisa® Quantitative Assays

Prod. No.	Name
ATG1010	Anti-TG
ATPO1020	Anti-TPO
BPTA0610	Bordetella pertussis toxin (PT) IgA
BPTG0610	Bordetella pertussis toxin (PT) IgG
CORG0090	Corynebacterium diphtheriae toxin IgG
CORG0090	Corynebacterium diphtheriae toxin 5S IgG
PCORG0090	Corynebacterium diphtheriae toxin 5S IgG plus
HE1A0220	Helicobacter pylori IgA
HE1G0220	Helicobacter pylori IgG
HE1A0300	Helicobacter pylori IgA plus
HE1G0300	Helicobacter pylori IgG plus
RFM3010	Rheumatoid Factor IgM
RUBG0400	Rubella Virus IgG
ARU37470	Arbovirus Rubella Virus IgG
TE1G5043	Clostridium tetani toxin IgG
TETG0043	Clostridium tetani 5S toxin IgG
PTETG043	Clostridium tetani toxin 5S IgG plus
TICG0440	Toxigenic Escherichia coli (EHEC) IgG
PTICG044	Toxigenic Escherichia coli (EHEC) IgG plus
TOXG0460	Toxoplasma gondii IgG
ATOX7460	Avdity Toxoplasma gondii IgG
TSH1030	TSH

Antigen Assays

Prod. No. Name

GIA0160S Giardia lamblia antigen

Novalisa[®] Igm µ-capture Assays

Prod. No. Name

CHIM0590 Chikungunya Virus Igm µ-capture

DVM0640 Dengue Virus Igm µ-capture

RUBM0400 Rubella Virus Igm µ-capture

TOXM0460 Toxoplasma gondii Igm µ-capture

ZVM0790 Zika Virus Igm µ-capture

Novalisa[®] Antibody Assays

Prod. No. Name

ASC.G0020 Ascaris lumbricoides IgG

CHAG0560 Chagas (Trypanosoma cruzi) IgG

TRY.P0570 Chagas

ENT.G0140 Entamoeba histolytica IgG

LEI.G0310 Leishmania infantum IgG

VAL.0670 Malaria

STR.O0690 Strongyloides

TAES0420 Taenia solium IgG

TOXG0450 Toxocara canis IgG

TRIG0480 Trichinella spiralis IgG

Novalisa[®] Avidity Assays

Prod. No. Name

AVV7110 Avidity Cytomegalovirus (CMV) IgG

EPV7150 Avidity Epstein-Barr Virus (VCA) IgG

MEV7330 Avidity Measles Virus IgG

RUB7400 Avidity Rubella Virus IgG

TOX7450 Avidity Toxoplasma gondii IgG

Novalisa[®] Liquor Diagnostic

Prod. No. Name

BORM0040 Borrelia burgdorferi IgG

BORM0040

Borrelia burgdorferi IgM

DICHIARAZIONE DI CONFORMITÀ CE / EC DECLARATION OF CONFORMITY

DICHIARAZIONE DI CONFORMITÀ CE

La società "Liofilchem" S.r.l., con Sede Legale in Via Scozia, 64026 Roseto degli Abruzzi (LE) Italia, in qualità di fabbricante del dispositivo medico-diagnostico *in vitro* elencato nella tabella allegata Revisione 31.0 of 08.01.2016

dichiara sotto la propria responsabilità

1. che il dispositivo sopra indicato soddisfa tutte le disposizioni applicabili della Direttiva 98/79/CE (Allegato III) recepite nella Legislazione Italiana dal Decreto Legislativo n° 332 del 8 settembre 2000;
2. che il dispositivo in oggetto non è incluso nell'Allegato II, Lista A e B della Direttiva 98/79/CE;
3. che la documentazione tecnica di cui all'allegato III della direttiva Direttiva 98/79/CE è a disposizione delle autorità nazionali presso la sua sede e sarà conservata per 5 anni dall'ultima data di fabbricazione del prodotto;
4. che il processo di fabbricazione segue adeguati principi di assicurazione della qualità;
5. di aver attivato e di mantenere aggiornato, un sistema di sorveglianza post-produzione per il prodotto in oggetto;
6. che il dispositivo in oggetto è stato messo in commercio munito di marcatura CE

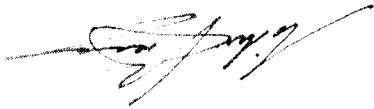
EC DECLARATION OF CONFORMITY

The company "Liofilchem" S.r.l., registered office in Via Scozia, 64026 Roseto degli Abruzzi (LE) Italy, as a manufacturer of the *in vitro* medical-diagnostic device listed in the attached table, Revision 31.0 of 08.01.2016 hereby certifies under its own responsibility

1. that the above mentioned device complies with all the applicable provisions of Directive 98/79/EC (Annex III) and its relevant transposition into national law;
2. the above mentioned is not included in Annex II, List A and B of Directive 98/79/EC;
3. that the technical documentation referred to at Annex III of the Directive 98/79/EC is available for the national authorities in its facility and that this documentation shall be kept for 5 years after the last production has been manufactured;
4. that the manufacturing process follows suitable principles of quality assurance;
5. that, has implemented and keep up to date, a post-production surveillance system for monitoring the products;
6. that the device in question, was introduced into the market provided with CE mark.

Roseto, 08.01.2016

Direttore Tecnico Technical Director
Dott. Silvio Brocco



Key Skills

[illegible]

Key words: depression; mood disorder; anxiety disorders; personality disorders; comorbidity; prevalence rates; risk factors; clinical presentation; treatment outcomes; research findings; clinical implications.

[illegible]

Rev 51.0 del 08.01.2016

[illegible]

Rev. 31.0 del 08.01.2016

[illegible]

Key: 51406

[illegible]

2000

[illegible]

Rev. 11 October 2018 01:29 (ex)

[illegible]

Key Messages

[illegible]

Rev. 3/10/2014

[illegible]

Rev. 310421(8.01.2016)

[illegible]

Rev. 310 de 08 of 2010

[illegible]

Key messages

[illegible]

10

Certificate



The Certification Body of
TÜV Rheinland LGA Products GmbH

TÜV Rheinland

Doc. 1/3, Rev. 0



LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

hereby certifies that the organization

EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Deutschland

Attachment to
Certificate
Registration No.:
Report No.:
SX 60129534 0001
21264033 005

Organization:
EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Deutschland

has established and applies a quality management system for medical devices
for the following scope

see attachment

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance

Scope:

Design and development, production, installation, service
and distribution of immunological test systems, immuno-
fluorescence test systems, molecular diagnostic/genetic
test systems, test systems for the determination of
infectious agents, the immunochemical software for
in vitro diagnosis.

Sites include:

EUROIMMUN Medizinische Labordiagnostika AG
Werstattstraße 2/22, 23560 Lübeck, Germany

Activities: Design and development, production, distribution

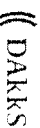
Effective Date: 2018-06-08

Certificate Registration No.: SX 60129534 0001

An audit was performed. Report No.: 21264033 005

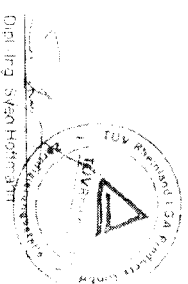
This Certificate is valid until: 2020-06-19

Certification Body



Deutsche
Angewandte
Normen
DIN 11601:02

Date: 2018-06-08



Officing: Stefan Hoffmann

TÜV Rheinland LGA Products GmbH, Tillystraße 2, 90431 Nürnberg



Deutsche
Angewandte
Normen
DIN 11601:02

Date: 2018-06-08

Issued by: Stefan Hoffmann





TÜVRheinland

TÜV Rheinland

Doc. 2/3, Rev. 0

IGA Products GmbH

Tillystraße 2, 90431 Nürnberg

TÜV Rheinland

Doc. 2/3, Rev. 0

IGA Products GmbH

Tillystraße 2, 90431 Nürnberg

Attachment to
Certificate
Registration No.:
Report No.:

SX 60129534 0001
21264033 005

Organization:

EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Deutschland

Attachment to
Certificate
Registration No.:
Report No.:

SX 60129534 0001
21264033 005

Organization:

EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Deutschland

Scope:

Items included:

EUROIMMUN Medizinische Labordiagnostika AG
Am Zinnenberg 9, 19629 Glüsby Burgau, Germany
Activities: Design and development, production
EUROIMMUN Medizinische Labordiagnostika AG
Am Zinnenberg 9, 19629 Glüsby Burgau, Germany
Activities: Design and development, distribution,
installation, service
EUROIMMUN Medizinische Labordiagnostika AG
Am Zinnenberg 9, 19629 Glüsby Burgau, Germany
Activities: Design and development, production, service

Scope:

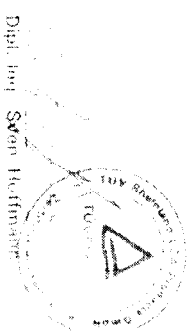
Items included:

EUROIMMUN Medizinische Labordiagnostika AG
Am Zinnenberg 9, 19629 Glüsby Burgau, Germany
Activities: Production
EUROIMMUN Medizinische Labordiagnostika AG
Am Zinnenberg 9, 19629 Glüsby Burgau, Germany
Activities: Production, installation, service
EUROIMMUN Medizinische Labordiagnostika AG
Am Zinnenberg 9, 19629 Glüsby Burgau, Germany
Activities: Design and development, production, service

DAKKS

DAKKS
Deutscher
Accreditation
Körperschaft

Date: 2018-06-15

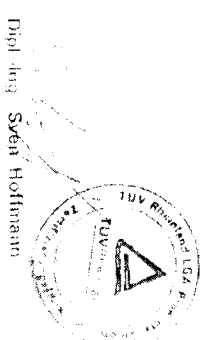


Certification Body

DAKKS

DAKKS
Deutscher
Accreditation
Körperschaft

Date: 2018-06-15



Certification Body



Si certifica che il

Sistema di Gestione per la Qualità

nesso in atto da

NUOVA APTACA S.r.l.

Via Monte Bianco, 4 - IT 20900 MONZA (MB)

nella Sede Operativa di

COGNITIVE UNIT

Regione Montforte, 30 - IT 14053 CANELLI (AT)

è conforme alla norma

is in compliance with the standard

UNI EN ISO 9001-2015 (ISO 9001-2015)

per i seguenti Processi:

62500797, 1997, 1998, 1999, 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019, 2020, 2021, 2022, 2023, 2024, 2025, 2026, 2027, 2028, 2029, 2030, 2031, 2032, 2033, 2034, 2035, 2036, 2037, 2038, 2039, 2040, 2041, 2042, 2043, 2044, 2045, 2046, 2047, 2048, 2049, 2050, 2051, 2052, 2053, 2054, 2055, 2056, 2057, 2058, 2059, 2060, 2061, 2062, 2063, 2064, 2065, 2066, 2067, 2068, 2069, 2070, 2071, 2072, 2073, 2074, 2075, 2076, 2077, 2078, 2079, 2080, 2081, 2082, 2083, 2084, 2085, 2086, 2087, 2088, 2089, 2090, 2091, 2092, 2093, 2094, 2095, 2096, 2097, 2098, 2099, 2100, 2101, 2102, 2103, 2104, 2105, 2106, 2107, 2108, 2109, 2110, 2111, 2112, 2113, 2114, 2115, 2116, 2117, 2118, 2119, 2120, 2121, 2122, 2123, 2124, 2125, 2126, 2127, 2128, 2129, 2130, 2131, 2132, 2133, 2134, 2135, 2136, 2137, 2138, 2139, 2140, 2141, 2142, 2143, 2144, 2145, 2146, 2147, 2148, 2149, 2150, 2151, 2152, 2153, 2154, 2155, 2156, 2157, 2158, 2159, 2160, 2161, 2162, 2163, 2164, 2165, 2166, 2167, 2168, 2169, 2170, 2171, 2172, 2173, 2174, 2175, 2176, 2177, 2178, 2179, 2180, 2181, 2182, 2183, 2184, 2185, 2186, 2187, 2188, 2189, 2190, 2191, 2192, 2193, 2194, 2195, 2196, 2197, 2198, 2199, 2200, 2201, 2202, 2203, 2204, 2205, 2206, 2207, 2208, 2209, 2210, 2211, 2212, 2213, 2214, 2215, 2216, 2217, 2218, 2219, 2220, 2221, 2222, 2223, 2224, 2225, 2226, 2227, 2228, 2229, 2230, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2238, 2239, 2240, 2241, 2242, 2243, 2244, 2245, 2246, 2247, 2248, 2249, 2250, 2251, 2252, 2253, 2254, 2255, 2256, 2257, 2258, 2259, 2260, 2261, 2262, 2263, 2264, 2265, 2266, 2267, 2268, 2269, 2270, 2271, 2272, 2273, 2274, 2275, 2276, 2277, 2278, 2279, 2280, 2281, 2282, 2283, 2284, 2285, 2286, 2287, 2288, 2289, 2290, 2291, 2292, 2293, 2294, 2295, 2296, 2297, 2298, 2299, 2300, 2301, 2302, 2303, 2304, 2305, 2306, 2307, 2308, 2309, 2310, 2311, 2312, 2313, 2314, 2315, 2316, 2317, 2318, 2319, 2320, 2321, 2322, 2323, 2324, 2325, 2326, 2327, 2328, 2329, 2330, 2331, 2332, 2333, 2334, 2335, 2336, 2337, 2338, 2339, 2340, 2341, 2342, 2343, 2344, 2345, 2346, 2347, 2348, 2349, 2350, 2351, 2352, 2353, 2354, 2355, 2356, 2357, 2358, 2359, 2360, 2361, 2362, 2363, 2364, 2365, 2366, 2367, 2368, 2369, 2370, 2371, 2372, 2373, 2374, 2375, 2376, 2377, 2378, 2379, 2380, 2381, 2382, 2383, 2384, 2385, 2386, 2387, 2388, 2389, 2390, 2391, 2392, 2393, 2394, 2395, 2396, 2397, 2398, 2399, 2400, 2401, 2402, 2403, 2404, 2405, 2406, 2407, 2408, 2409, 2410, 2411, 2412, 2413, 2414, 2415, 2416, 2417, 2418, 2419, 2420, 2421, 2422, 2423, 2424, 2425, 2426, 2427, 2428, 2429, 2430, 2431, 2432, 2433, 2434, 2435, 2436, 2437, 2438, 2439, 2440, 2441, 2442, 2443, 2444, 2445, 2446, 2447, 2448, 2449, 2450, 2451, 2452, 2453, 2454, 2455, 2456, 2457, 2458, 2459, 2460, 2461, 2462, 2463, 2464, 2465, 2466, 2467, 2468, 2469, 2470, 2471, 2472, 2473, 2474, 2475, 2476, 2477, 2478, 2479, 2480, 2481, 2482, 2483, 2484, 2485, 2486, 2487, 2488, 2489, 2490, 2491, 2492, 2493, 2494, 2495, 2496, 2497, 2498, 2499, 2500, 2501, 2502, 2503, 2504, 2505, 2506, 2507, 2508, 2509, 2510, 2511, 2512, 2513, 2514, 2515, 2516, 2517, 2518, 2519, 2520, 2521, 2522, 2523, 2524, 2525, 2526, 2527, 2528, 2529, 2530, 2531, 2532, 2533, 2534, 2535, 2536, 2537, 2538, 2539, 2540, 2541, 2542, 2543, 2544, 2545, 2546, 2547, 2548, 2549, 2550, 2551, 2552, 2553, 2554, 2555, 2556, 2557, 2558, 2559, 2560, 2561, 2562, 2563, 2564, 2565, 2566, 2567, 2568, 2569, 2570, 2571, 2572, 2573, 2574, 2575, 2576, 2577, 2578, 2579, 2580, 2581, 2582, 2583, 2584, 2585, 2586, 2587, 2588, 2589, 2590, 2591, 2592, 2593, 2594, 2595, 2596, 2597, 2598, 2599, 2600, 2601, 2602, 2603, 2604, 2605, 2606, 2607, 2608, 2609, 2610, 2611, 2612, 2613, 2614, 2615, 2616, 2617, 2618, 2619, 2620, 2621, 2622, 2623, 2624, 2625, 2626, 2627, 2628, 2629, 2630, 2631, 2632, 2633, 2634, 2635, 2636, 2637, 2638, 2639, 2640, 2641, 2642, 2643, 2644, 2645, 2646, 2647, 2648, 2649, 2650, 2651, 2652, 2653, 2654, 2655, 2656, 2657, 2658, 2659, 2660, 2661, 2662, 2663, 2664, 2665, 2666, 2667, 2668, 2669, 2670, 2671, 2672, 2673, 2674, 2675, 2676, 2677

Gestione della fabbricazione ed immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifici naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi. Commercializzazione di dispositivi medici e diagnostici in vitro. Commercializzazione di articoli da laboratorio

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Marketing of medical and diagnostic devices in vitro. Marketing of laboratory articles.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dal Regolamento in vigore applicabili

This (and the shift study) the experimenters published in the *Times* for the scientists to read, but the

in caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana.

L'AMMINISTRATORE DELEGATO

NOT RECORDED

W. B. E. B.

Dr. Ing. Roberto Cusolito

Data di Prima Emissione:

Data di Prima Emissione ITALCERT

First Issue Date: 11/1/1997

Review Date

14. *Chlorophyll a* (Chl *a*)

1998-07-23

Settore IAF 14 - 29



566 N° 0214
567 N° 0200
568 N° 075E
569 N° 122H
570 N° 0210

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CERTIFICATO N° 505DM05

CERTIFICATE N° 505DM05

Si certifica che il

this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messso in atto da

implemented by

NUOVA APTACA S.r.l.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di

Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma

is in compliance with the standard

UNI CEI EN ISO 13485-2016 (ISO 13485-2016)

per i seguenti Processi

concerning the following kinds of Processes

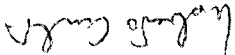
Gestione della fabbricazione e immissione in commercio di tamponi sterili
per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico.
Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi.
Commercializzazione di dispositivi medici e diagnostici in vitro.

Management of manufacturing and placing on the market of sterile tampons for sampling of biological specimens in
natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for medical laboratories
Marketing of medical and diagnostic devices in vitro.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dal Regolamento per la certificazione in vitro applicabile
in caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana.
The present Certificate is subject to the conditions established by the Regulation for in vitro certification applicable in case of discrepancy between the languages used in the translation of the content of the present certificate, refer to the Italian language.

L'AMMINISTRATORE DELEGATO

MANAGING DIRECTOR



Dr. Ing. Roberto Cusotto

Data di Prima Emissione	Data di Prima Emissione ITALCERT	Data di Rinnovo	Data di Delibera	Data di Scadenza
2007-10-30	2011-10-30	2017-10-30	2019-01-04	2020-10-29



505 N° 023A
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