Сертификат

mdc medical device certification GmbH
удостоверяет, что на предприятии

ВЕКТОР БЕСТ

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	2020-07-04
Срок действия до	2023-07-03
Регистрационный №	D1213100019
Отчет №	P20-00568-173687
Штутгарт, Германия	2020-06-02

Руководитель сертификационного органа

Digitally signed by Ceaicovschi Tudor
Date: 2021.04.23 08:54:45 EEST
Reason: MoldSign Signature
Location: Moldova

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Приложение к Сертификату

№ D1213100019 от 2020-06-02 Стр. 1 из 1

Месторасположение	**Область действия**
АО «Вектор-Бест», ул. Арбузова, 1/1, 630117, г. Новосибирск, Российская Федерация	проектирование и разработка, производство и реализация 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

medical device certification mdc

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

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 TTV-IgG	ELISA kit for determination of IgG to TT 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.	VectoParotitis-IgG	ELISA kit for determination of IgG to parotitis virus	D-2602
20.	VectoParotitis-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

		antigens	
24.	Ascarid-IgG-EIA-BEST	ELISA kit for determination of IgG to Ascaris lumbricoides	D-3452
25.	Lamblia-antibodies-EIA-BEST	ELISA kit for determination of IgG, IgM and IgA to Lamblia antibodies	D-3552
26.	Lamblia-IgM-EIA-BEST	ELISA kit for determination of IgM to Lamblia antibodies	D-3554
27.	Lamblia-antigen-EIA-BEST	ELISA kit for determination of Lamblia antigen	D-3556
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
61.	HBsAg-EIA-BEST kit 2	ELISA kit for the detection of HBs-antigen.	D-0543
62.	HBsAg-EIA-BEST kit 3	ELISA kit for the detection of HBs-antigen.	D-0544
63.	VectoHBcAg-antibodies	ELISA kit for the detection of total antibodies against hepatitis B core-antigen	D-0566
64.	HepaBest anti-HBc-IgG	Enzyme immunoassay kit for the detection of IgG against hepatitis B core-antigen	D-0574
65.	Best anti-HCV (set 3)	Enzyme immunoassay kit for the detection of IgG and IgM against hepatitis C virus.	D-0773
66.	Best anti-HCV (set 2)	Enzyme immunoassay kit for the detection of IgG and IgM against hepatitis C virus.	D-0772
67.	Vectohep D-IgM	Enzyme immunoassay kit for the detection of IgM against hepatitis D virus	D-0952
68.	Chlamydia tr. IgG-EIA-BEST	ELISA kit for determination of IgG to Chlamidia trachomatis	D-1964
69.	Chlamydia tr. IgM-EIA-BEST	ELISA kit for determination of IgM to Chlamidia trachomatis	D-1966
70.	Chlamydia tr. IgA-EIA-BEST	ELISA kit for determination of IgA to Chlamidia trachomatis	D-1968
71.	CMV-IgG-EIA-BEST	ELISA kit for the qualitative and quantitative determination of IgG against Cytomegalovirus	D-1556
72.	VectoCMV-IgM	ELISA kit for the detection of IgM against Cytomegalovirus	D-1552

Certificate

mdc medical device certification GmbH
certifies that

VECTOR BEST

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 this quality management system meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems – Requirements for regulatory purposes

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

Valid from	2020-07-04
Valid until	2023-07-03
Registration no.	D1213100019
Report no.	P20-00568-173687
Stuttgart	2020-06-02

Head of Certification Body

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Attachment of the certificate

No. D1213100019 date 2020-06-02 Page 1 of 1

Location	Scope
AO Vector-Best Arbuzova 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

medical device certification mdc

Head of Certification Body

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Ministero della Salute
DGFDM
0043588-P-26/10/2011

96082548

Ministero dell'Economia e delle Finanze MARCA DA BOLLO €14,62 QUATTORDICI/62
Agenzia Entrate
00011148 00008968 WDBATD01
00468407 29/06/2011 08:42:26
0001-00009 E3A3A5A456EF68C3
IDENTIFICATIVO : 01092857617099
0 1 09 285761 709 9

Ministero della Salute

DIPARTIMENTO DELLA PROGRAMMAZIONE E DELL'ORDINAMENTO DEL SERVIZIO SANITARIO NAZIONALE
DIREZIONE GENERALE DEI DISPOSITIVI MEDICI, DEL SERVIZIO FARMACEUTICO E DELLA SICUREZZA DELLE CURE
UFFICIO IV ex DGFDM – DIAGNOSTICI IN VITRO

I.5.l.e.2/IV/2011/37

VISTA la direttiva 98/79/CE relativa ai dispositivi medico-diagnostici in vitro;
VISTO il D.lgs. n .332/2000 recante attuazione della direttiva 98/79/CE;
VISTA l'istanza del 29/09/2011 presentata dalla ditta Dia.Pro Diagnostic Bioprobes Srl con sede in Via G.Carducci, 27 – 20099 Sesto San Giovanni (MI) – C.F./P.Iva 11924660159;
CONSIDERATO che la ditta istante ha effettuato i versamenti richiesti dal D.M. 24 Maggio 2004;
VISTI gli atti d'ufficio;
HAVING REGARD *to 98/79/EC directive concerning the in vitro diagnostic medical-devices;*
HAVING REGARD *to legislative Decree (D.lgs.)n. 332/2000 reporting the accomplishment of 98/79/EC Directive;*
HAVING REGARD to *the request dated 29/09/2011 submitted by the company* Dia.Pro Diagnostic Bioprobes Srl con with legal site in Via Columella, 31 – 20128 Milano – C.F. and P.Iva 11924660159;
WHEREAS *this company paid the fees required by Ministerial Decree (D.M.) May 24, 2004;*
HAVING REGARD to *the official deeds;*

SI ATTESTA
IT IS ATTESTED

che la ditta, Dia.Pro Diagnostic Bioprobes Srl con sede in Via G.Carducci, 27 – 20099 Sesto San Giovanni (MI) – C.F./P.Iva 11924660159, ha prodotto e marcato CE, come dispositivo medico- diagnostico in vitro, secondo le procedure previste dalla direttiva 98/79/CE, il prodotto:
that the Company Dia.Pro Diagnostic Bioprobes Srl located in Via G.Carducci, 27 – 20099 Sesto San Giovanni (MI) – C.F./P.Iva 11924660159, manufactured and affixed CE marking as in vitro diagnostic medical device, according to the Directive 98/79/EC, the following product:

DP-9 DIA.BLOOD INSTRUMENT

Il suddetto prodotto, in base all'art. 4 della direttiva 98/79/CE, è di libera circolazione e può essere messo in commercio in Italia e in tutto il territorio dell'Unione Europea.

Si rilascia il presente attestato su richiesta dell'interessato per gli usi consentiti dalla legge e per l'esportazione nei paesi extra UE.

The above mentioned product, according to the art. 4 of 98/79/EC directive, can freely circulate and can be commercialized in Italy and in the whole of the European Union. This certificate is issued on the interested company's request according to the law and to export to non-European countries

IL DIRETTORE DELL'UFFICIO IV
(Dott.ssa Giovanna Nisticò)

IC/CM

Dia.Pro
Diagnostic
BioProbes

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.

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 S.r.l.

Rev:	12/2013

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1483000-1

Organization:
EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

Scope: Design and development, manufacture, installation, service and distribution of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents, and instruments / software for in vitro diagnostics

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 3313978-90

Effective date: 2020-05-19

Expiry date: 2023-05-18

Issue date: 2020-05-14

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

D. Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1483000-1

Organization: EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

No.	Facility	Scope
/01	EUROIMMUN Medizinische Labordiagnostika AG Seekamp 31 23560 Lübeck Germany	Design and development and manufacture of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents, and instruments / software for instruments for in vitro diagnostics
/02	EUROIMMUN Medizinische Labordiagnostika AG Werkstr. 1 23942 Dassow Germany	Design, development, manufacture and distribution of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents and instruments / software for in vitro diagnostics
/03	EUROIMMUN Medizinische Labordiagnostika AG An der Trave 1 23923 Selmsdorf Germany	Design, development, manufacture, service and distribution of immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents and instruments / software for in vitro diagnostics

Report No.: 3313978-90

Effective date: 2020-05-19

Expiry date: 2023-05-18

Issue date: 2020-05-14

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1483000-1

Organization:
EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

/04	EUROIMMUN Medizinische Labordiagnostika AG Am Sonnenberg 9 23627 Groß Grönau Germany	Design, development and manufacture of immunofluorescence test systems, molecular diagnostic / genetic test systems and, test systems for the determination of infectious agents for in vitro diagnostics
/05	EUROIMMUN Medizinische Labordiagnostika AG Am Born 24 23627 Groß Grönau Germany	Design and development of software for in vitro diagnostics
/06	EUROIMMUN Medizinische Labordiagnostika AG Im Kreppel 1 02747 Herrnhut Germany	Manufacture of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems and test systems for the determination of infectious agents for in vitro diagnostics
/07	EUROIMMUN Medizinische Labordiagnostika AG Am Pließnitztal 1 02748 Bernstadt Germany	Manufacture of immunobiochemical test systems, test systems for the determination of infectious agents and instruments for in vitro diagnostics

Report No.: 3313978-90

Effective date: 2020-05-19

Expiry date: 2023-05-18

Issue date: 2020-05-14

TÜV Rheinland LGA Products GmbH · TÜVRheinland · Zertifizierungsstelle

D. Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1483000-1

Organization:
EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

/08	EUROIMMUN Medizinische Labordiagnostika AG Schloßstr. 11 91257 Pegnitz Germany	Manufacture of immunofluorescence test systems, installation and service of instruments / software for in vitro diagnostic
/09	EUROIMMUN Medizinische Labordiagnostika AG Am Flugplatz 4 23560 Lübeck Germany	Installation, service and distribution of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents, and instruments / software for in vitro diagnostics
/10	EUROIMMUN Medizinische Labordiagnostika AG Gewerbestr. 19 23942 Dassow Germany	Manufacture of sheet metal and other components for instruments for in vitro diagnostics

Report No.: 3313978-90

Effective date: 2020-05-19

Expiry date: 2023-05-18

Issue date: 2020-05-14

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

D. Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810000**

Certificate Holder: **EUROIMMUN**
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

including the locations according to annex

Scope: Design, development, manufacture, installation, service and sales of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents, and instruments / software for in vitro diagnostics in humans and animals; trainings

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2020-05-19 until 2023-05-18.
First certification 2018

2020-05-14

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810000**

No.	Location	Scope
/01	EUROIMMUN Medizinische Labordiagnostika AG Seekamp 31 23560 Lübeck Germany	Design, development, manufacture, installation, service and sales of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents, and instruments / software for in vitro diagnostics in humans and animals; trainings
/02	EUROIMMUN Medizinische Labordiagnostika AG Werkstr. 1 23942 Dassow Germany	Design, development, manufacture and sales of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents and instruments / software forin vitro diagnostics in humans and animals
/03	EUROIMMUN Medizinische Labordiagnostika AG An der Trave 1 23923 Selmsdorf Germany	Design, development, manufacture, service and sales of immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents and instruments / software for in vitro diagnostics in humans
/04	EUROIMMUN Medizinische Labordiagnostika AG Am Sonnenberg 9 23627 Groß Grönau Germany	Design, development and manufacture of immunofluorescence test systems, molecular diagnostic / genetic test systems, and test systems for the determination of infectious agents for in vitro diagnostics inhumans and animals
/05	EUROIMMUN Medizinische Labordiagnostika AG Am Born 24 23627 Groß Grönau Germany	Design and development of software for in vitro diagnostics for humans

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810000**

/06	EUROIMMUN Medizinische Labordiagnostika AG Im Kreppel 1 02747 Herrnhut Germany	Manufacture of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems and test systems for the determinationof infectious agents for in vitro diagnosticsin humans
/07	EUROIMMUN Medizinische Labordiagnostika AG Am Pließnitztal 1 02748 Bernstadt Germany	Manufacture of immunobiochemical test Systems, test systems for the determination of infectious agents and instruments for in vitro diagnostics for humans
/08	EUROIMMUN Medizinische Labordiagnostika AG Schloßstr. 11 91257 Pegnitz Germany	Manufacture of immunofluorescence test systems, installation and service of instruments / software for in vitro diagnostics in humans, trainings
/09	EUROIMMUN Medizinische Labordiagnostika AG Am Flugplatz 4 23560 Lübeck Germany	Installation, service and sales of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents and instruments / software for in vitro diagnostics for humans and animals
/10	EUROIMMUN Medizinische Labordiagnostika AG Gewerbestr. 19 23942 Dassow Germany	Manufacture of sheet metal and other components for instruments for in vitro diagnostics in humans and animals

2020-05-14

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Certificate

TÜVRheinland®

Certificate No.:	MD 3313978-150
Manufacturer:	**EUROIMMUN** **Medizinische Labordiagnostika AG** Seekamp 31 23560 Lübeck Germany
D-U-N-S No.:	322209263
Certification criteria:	ISO 13485:2016 Australia Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure Brazil RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009 Canada Medical Devices Regulations – Part 1 – SOR 98/282 Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D
Scope:	Design, development, manufacture, installation, service and distribution of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents, and instruments / software for in vitro diagnostics

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.:	3313978-150
Issue Date:	2020-05-14
Effective Date:	2020-05-19
Expiry Date:	2023-05-18

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

D. Wiedemuth

Certification officer: Dipl.-Ing. (FH) D. Wiedemuth
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified by calling 1-888-743-4652.

TUV Rheinland of North America, Inc., 12 Commerce Road, Newtown, CT 06470, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

Certificate

TÜVRheinland®

Certificate No.: MD 3313978-150

Manufacturer: **EUROIMMUN**
Medizinische Labordiagnostika AG

Seekamp 31
23560 Lübeck
Germany

No.	Location	Scope
/01	EUROIMMUN Medizinische Labordiagnostika AG Seekamp 31 23560 Lübeck Germany D-U-N-S No.: 322209263	Design, development and manufacture of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents, and instruments / software for in vitro diagnostics
/02	EUROIMMUN Medizinische Labordiagnostika AG Am Born 24 23627 Groß Grönau Germany D-U-N-S No.: 313547785	Design and development of software for in vitro diagnostics
/03	EUROIMMUN Medizinische Labordiagnostika AG Am Sonnenberg 9 23627 Groß Grönau Germany D-U-N-S No.: 313547785	Design, development and manufacture of immunofluorescence test systems, molecular diagnostic / genetic test systems and, test systems for the determination of infectious agents for in vitro diagnostics

Project No.: 3313978-150

Issue Date: 2020-05-14

Effective Date: 2020-05-19

Expiry Date: 2023-05-18

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Certificate No.: MD 3313978-150

Manufacturer: **EUROIMMUN**
Medizinische Labordiagnostika AG

Seekamp 31
23560 Lübeck
Germany

/04	EUROIMMUN Medizinische Labordiagnostika AG Am Pließnitztal 1 02748 Bernstadt Germany D-U-N-S No.: 313547786	Manufacture of immunobiochemical test systems, test systems for the determination of infectious agents and instruments for in vitro diagnostics
/05	EUROIMMUN Medizinische Labordiagnostika AG Im Kreppel 1 02747 Herrnhut Germany D-U-N-S No.: 342488345	Manufacture of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems and test systems for the determination of infectious agents for in vitro diagnostics
/06	EUROIMMUN Medizinische Labordiagnostika AG Schloßstr. 11 91257 Pegnitz Germany D-U-N-S No.: 342488344	Manufacture of immunofluorescence test systems, installation and service of instruments / software for in vitro diagnostic

Project No.: 3313978-150
Issue Date: 2020-05-14
Effective Date: 2020-05-19
Expiry Date: 2023-05-18

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Certificate

TÜVRheinland®

Certificate No.: MD 3313978-150

Manufacturer:

EUROIMMUN
Medizinische Labordiagnostika AG

Seekamp 31
23560 Lübeck
Germany

/07	EUROIMMUN Medizinische Labordiagnostika AG An der Trave 1 23923 Selmsdorf Germany D-U-N-S No.: 313773638	Design, development, manufacture, service and distribution of immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents and instruments / software for in vitro diagnostics
/08	EUROIMMUN Medizinische Labordiagnostika AG Werkstr. 1 23942 Dassow Germany D-U-N-S No.: 342488342	Design, development, manufacture and sales of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents and instruments / software for in vitro diagnostics
/09	EUROIMMUN Medizinische Labordiagnostika AG Gewerbestr. 19 23942 Dassow Germany D-U-N-S No.: 342488342	Manufacture of sheet metal and other components for instruments for in vitro diagnostics

Project No.: 3313978-150

Issue Date: 2020-05-14

Effective Date: 2020-05-19

Expiry Date: 2023-05-18

MDSAP
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Certificate No.: MD 3313978-150

Manufacturer:

EUROIMMUN
Medizinische Labordiagnostika AG

Seekamp 31
23560 Lübeck
Germany

/10	EUROIMMUN Medizinische Labordiagnostika AG Am Flugplatz 4 23560 Lübeck Germany D-U-N-S No.: 322209263	Installation, service and distribution of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents, and instruments / software for in vitro diagnostics

Project No.: 3313978-150
Issue Date: 2020-05-14
Effective Date: 2020-05-19
Expiry Date: 2023-05-18

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Certificate No. 3868-7-2011

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)	**Name of Manufacturer/Distributor Address**
See Attached List (Two Pages)	Manufacturer: Monobind, Inc. 100 North Pointe Drive Lake Forest, CA 92630. Distributor: Monobind, Inc. 100 North Pointe Drive Lake Forest, CA 92630.

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the products(s) listed above.

Ann M. Ferriter
Acting Director
Division of Risk Management Operations
Office of Compliance
Center for Devices and Radiological Health

This certificate expires 24 months from the date notarized.

COUNTY OF MONTGOMERY
STATE OF MARYLAND

Subscribed and sworn to before me this 10 day of Aug month 2011 year.

CATHRYN N. MORRIS
NOTARY PUBLIC STATE OF MARYLAND
County of Montgomery
My Commission Expires January 4, 2013

Certificate to Foreign Government – Attachment (Page 1 of 2)

NAME OF PRODUCT(S)

Total T3 TEST SYSTEM
Total T4 TEST SYSTEM
Free T4 TEST SYSTEM
Free T3 TEST SYSTEM
TSH TEST SYSTEM
T3 Uptake TEST SYSTEM
TBG TEST SYSTEM
Tg TEST SYSTEM
N-T4 TEST SYSTEM
N-TSH TEST SYSTEM
N-17-OHP TEST SYSTEM
Anti-Tg TEST SYSTEM
Anti-TPO TEST SYSTEM
LH TEST SYSTEM
FSH TEST SYSTEM
PRL TEST SYSTEM
HCG TEST SYSTEM
Cortisol TEST SYSTEM
Testosterone TEST SYSTEM
Free Testosterone TEST SYSTEM
Progesterone TEST SYSTEM
17-OH Progesterone TEST SYSTEM
Estradiol TEST SYSTEM
Estriol TEST SYSTEM
DHEA-S TEST SYSTEM
DHEA TEST SYSTEM
HGH TEST SYSTEM
Insulin TEST SYSTEM
C-Peptide TEST SYSTEM
IgE TEST SYSTEM
Ferritin TEST SYSTEM
Transferrin Soluble Receptor TEST SYSTEM
Vit B12 TEST SYSTEM
Folate TEST SYSTEM
Creatine Kinase TEST SYSTEM
Digoxin TEST SYSTEM
hsCRP TEST SYSTEM
Myoglobin TEST SYSTEM
cTnI TEST SYSTEM
H. Pylori Ab TEST SYSTEM
HbSAg TEST SYSTEM

NAME OF MANUFACTURER/DISTRIBUTOR, ADDRESS

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

Certificate to Foreign Government – Attachment (Page 2 of 2)

NAME OF PRODUCT(S)

Rubella TEST SYSTEM
Toxoplasma TEST SYSTEM
AFP TEST SYSTEM
CEA TEST SYSTEM
tPSA TEST SYSTEM
fPSA TEST SYSTEM
CA-125 TEST SYSTEM
CA-19-9 TEST SYSTEM
CA-15-3 TEST SYSTEM
Free Beta hCG TEST SYSTEM
Mulit-Ligand Quality Control Material
Cardiac Panel Quality Control Material
Tumor Marker Quality Control Material
Thyroid Panel Quality Control Material
Fertility Quality Control Material

TEST SYSTEMS available in ELISA (AccuBind®), CLIA (AccuLite®) and VAST® formats.
Quality Control Material available in (QSure®) Assayed and Unassayed formats.

Lumax® CLIA Analyzer
NeoLumax™ CLIA Analyzer
LuMatic™ CLIA Analyzer
Lumax-96™ CLIA Analyzer
Impulse 2™ CLIA Analyzer
Impulse3™ CLIA Analyzer
Eldex 3.8® ELISA Analyzer
NeoEldex™ ELISA Analyzer
Autoplex™ ELISA & CLIA Analyzer
Immunoassay Plate Washer

"END OF PRODUCT LIST"

NAME OF MANUFACTURER/DISTRIBUTOR, ADDRESS

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

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

Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

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:

The Design, Manufacture and Distribution of In-Vitro Diagnostic Medical Device Immunoassays and Related Reagents, Controls, and Semi-Manual and Automated Washers and Analyzers.

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:
Caroline Dore Geraghty
Director of Medical Devices /
Head of Notified Body

Registration Number: MD19.4585
Certification Granted: May 18, 2010
Effective Date: September 25, 2019
Expiry Date: September 24, 2022

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800

Annex to Certificate Number: MD19.4585

Scope of Registration:

The Design, Manufacture and Distribution of In-Vitro Diagnostic Medical Device Immunoassays and Related Reagents, Controls, and Semi-Manual and Automated Washers and Analyzers.

Activity	Location
Headquarters, Administration, Design, Manufacturing, Distribution	Monobind Inc. 100 North Pointe Drive Lake Forest, CA 92630 USA File No.: MD19.4585
Manufacturing, Distribution	Monobind Inc. 103 North Pointe Drive Lake Forest, CA 92630 USA File No.: MD19.4585/A

Verified by:
Operations Manager