

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 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



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



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Head of Certification Body

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



Руководитель сертификационного органа



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



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Руководитель сертификационного органа

	ZAO "Vector-Best"	Rev. 01
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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:

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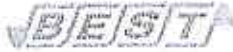
Date: 2013/04/12



Murat Khusainov
General Director ZAO «Vector-Best»

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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

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		antigens	
24.	Ascarid-IgG-EIA-BEST	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-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

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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