

	ZAO "Vector-Best" EC Declaration of conformity	Rev. 01 Page 1 of 4
---	--	------------------------

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

Biorori 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»



VECTIV

BEST

ZAO "Vector-Best"

EC Declaration of conformity

Rev. 01

Page 2 of 4

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-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



VECTOR

BEST

ZAO "Vector-Best"

EC Declaration of conformity

Rev. 01

Page 3 of 4

		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



BEST

ZAO "Vector-Best"

Rev. 01

EC Declaration of conformity

Page 4 of 4

46.	Ferritin-EIA-BEST	ELISA kit for determination of concentration of ferritin	T-8652
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-8762
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 pro-hormone 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.	VectorHBcAg-antibodies	ELISA kit for the detection of total antibodies against hepatitis B core-antigen	D-0566
64.	Hexabest 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.	VectorHep 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 Chlamydia trachomatis	D-1964
69.	Chlamydia tr. IgM-EIA-BEST	ELISA kit for determination of IgM to Chlamydia trachomatis	D-1966
70.	Chlamydia tr. IgA-EIA-BEST	ELISA kit for determination of IgA to Chlamydia trachomatis	D-1968
71.	CMV-IgG-EIA-BEST	ELISA kit for the qualitative determination of IgG to Cytomegalovirus	D-1556
72.	VectorCMV-IgM	ELISA kit for the qualitative determination of IgM to Cytomegalovirus	D-1552



