Vitrotest	EC DECLARATION OF CONFORMITY			
ELISA kits & components	No DoC_Ascaris_	lumbricoides_lgG_EL051-96	1st ed.	P. 1 of 1
MANUFACTURER:		Vitrotest Europe Sp. z O	.0.	
ADDRESS:		Krakowska str., 139-155	, 50-428, Wro	claw, Poland
PRODUCT NAME:		Vitrotest Ascaris lumbrid ELISA test kit for the det Ascaris lumbricoides		class antibodies to
PRODUCT CATALO	OGUE NUMBER:	EL051-96		
GMDN CODE:		52133		
We hereby declare that the above mentioned product meet the provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.				
CLASSIFICATION:		In vitro medical device, o A or B of Annex II of D for self-testing, not for per	irective 98/79/	/EC, not a product
CONFORMITY ROU	JTE:	Annex III of Directive 98/	79/EC.	
APPLICABLE STANDARDS:		EN ISO 13485:2016; EN ISO 14971:2019; EN 13612:2002; EN ISO 15223-1:2016; EN ISO 23640:2015. EN ISO 23640:2015.		13-2:2011;
This Declaration of conformity is issued under the responsibility of the manufacturer.				rer.
Edition 1	Wro	Issued in	15.	.02.2022 Date

Vitrotest Europe Sp. z o.o. ul. Krakowska 139-155, 50-428 Wrocław NIP: 8992881308, REGON: 386329301 KRS: 0000844411

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Vitrotest	EC DECLARATION OF CONFORMITY			
ELISA kits & components	No DoC_B	orrelia_lgG_EL084-96	1st ed.	P. 1 of 1
MANUFACTURER:		Vitrotest Europe Sp. z O).0.	
ADDRESS:		Krakowska str., 139-155	5, 50-428, Wrod	claw, Poland
PRODUCT NAME:		Vitrotest Borrelia IgG ELISA test kit for the qualitative and semiquantitative determination of IgG class antibodies to <i>Borrelia</i> <i>burgdorferi sensu lato</i>		
PRODUCT CATALO	GUE NUMBER:	EL084-96		
GMDN CODE:		63901		
We hereby declare that the above mentioned product meet the provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.				
CLASSIFICATION:		In vitro medical device, of A or B of Annex II of D for self-testing, not for per	Directive 98/79/	EC, not a product
CONFORMITY ROU	JTE:	Annex III of Directive 98,	/79/EC.	
APPLICABLE STANDARDS:		EN ISO 13485:2016; EN ISO 14971:2019; EN 13612:2002; EN ISO 15223-1:2016;	EN ISO 1811 EN ISO 1811 EN ISO 2364	3-2:2011;
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Edition 1	Wr	oclaw, Poland Issued in	21.	02.2022 Date
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EC DECLARATION OF CONFORMITY

No DoC_Borrelia_IgM_EL085-96

1st ed.

P. 1 of 1

MANUFACTURER:	Vitrotest Europe Sp. z O.O.	
ADDRESS:	Krakowska str., 139-155, 50-428, Wroclaw, Poland	
PRODUCT NAME:	Vitrotest Borrelia IgM ELISA test kit for the qualitative and semiquantitative determination of IgM class antibodies to <i>Borrelia</i> <i>burgdorferi sensu lato</i>	
PRODUCT CATALOGUE NUMBER:	EL085-96	
GMDN CODE:	63059	

We hereby declare that the above mentioned product meet the provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

CLASSIFICATION:In vitro medical device, other device (not applicable to list
A or B of Annex II of Directive 98/79/EC, not a product
for self-testing, not for performance evaluation).

CONFORMITY ROUTE:

Annex III of Directive 98/79/EC.

APPLICABLE STANDARDS:

EN ISO 13485:2016; EN ISO 14971:2019; EN 13612:2002; EN ISO 15223-1:2016; EN ISO 18113-1:2011; EN ISO 18113-2:2011; EN ISO 23640:2015.

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Vitrotest	EC DECLARATION OF CONFORMITY			Y
ELISA kits & components	No DoC_Helicob	acter_pylori_lgA_EL099-96	1st ed.	P. 1 of 1
MANUFACTURER:		Vitrotest Europe Sp. z O.	.0.	
ADDRESS:		Krakowska str., 139-155,	50-428, Wro	claw, Poland
PRODUCT NAME:		Vitrotest Helicobacter py ELISA test kit for the o determination of IgA cla pylori	qualitative and	
PRODUCT CATALOGUE NUMBER:		EL099-96		
GMDN CODE:		51004		
We hereby declare that the above mentioned product meet the provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medica devices.				
CLASSIFICATION:		In vitro medical device, ot A or B of Annex II of Di for self-testing, not for perf	rective 98/79/	EC, not a product
CONFORMITY ROUTE:		Annex III of Directive 98/7	79/EC.	
APPLICABLE STANDARDS:		EN ISO 13485:2016; EN ISO 14971:2019; EN 13612:2002; EN ISO 15223-1:2016;	EN ISO 1811 EN ISO 1811 EN ISO 2364	3-2:2011;

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Edition 1

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Calipie	Mirest Europe Sp. z o.o. ul Krakowska 197-155, 50-428 Wrocław NIP: 8992881308, REGON: 386329301 KRS: 0000844411

25.02.2022 Date

Vitrotest	EC DECLARATION OF CONFORMITY			ſY
ELISA kits & components	No DoC_Helicob	pacter_pylori_lgG_EL098-96	1st ed.	P. 1 of 1
MANUFACTURER:		Vitrotest Europe Sp. z O	.0.	
ADDRESS:		Krakowska str., 139-155	, 50-428, Wro	claw, Poland
PRODUCT NAME:		Vitrotest Helicobacter py ELISA test kit for the determination of IgG cl pylori	qualitative and	
PRODUCT CATALO	OGUE NUMBER:	EL098-96		
GMDN CODE:		51008		
We hereby declare that the above mentioned product meet the provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.				
CLASSIFICATION:		In vitro medical device, o A or B of Annex II of D for self-testing, not for per	irective 98/79	EC, not a product
CONFORMITY ROU	JTE:	Annex III of Directive 98/	79/EC.	
APPLICABLE STANDARDS:		EN ISO 13485:2016; EN ISO 14971:2019; EN 13612:2002; EN ISO 15223-1:2016;	EN ISO 181 EN ISO 181 EN ISO 2364	13-2:2011;
This Declaration of o	conformity is issued u	nder the responsibility of t	he manufactu	rer.
Edition 1	Wr	oclaw, Poland	25.	.02.2022

Wroclaw, Poland Issued in Calyng Roylvship

Galyna Rayevska, Ph.D.

Chief of the Board

Date

Vitrotest Europe Sp. z o.o. ul. Krakowska 139-155, 50-428 Wrocław NIP: 8992881308, REGON: 386329301 KRS: 0000844411

Vitrotest	EC	DECLARATION OF CO	ONFORMI	ſY
ELISA kits & components	No DoC_Toxoc	cara_canis_lgG_EL058-96	1st ed.	P. 1 of 1
MANUFACTURER:		Vitrotest Europe Sp. z O.	0.	
ADDRESS:		Krakowska str., 139-155,	50-428, Wro	claw, Poland
PRODUCT NAME:		Vitrotest Toxocara canis ELISA test kit for the dete Toxocara canis	-	class antibodies to
PRODUCT CATALC	GUE NUMBER:	EL058-96		
GMDN CODE:		52418		
We hereby declare that the above mentioned product meet the provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medica devices.				
CLASSIFICATION:		In vitro medical device, ot A or B of Annex II of Di for self-testing, not for perf	rective 98/79	/EC, not a product
CONFORMITY ROUTE:		Annex III of Directive 98/7	79/EC.	
APPLICABLE STANDARDS:		EN ISO 13485:2016; EN ISO 14971:2019; EN 13612:2002; EN ISO 15223-1:2016;	EN ISO 181 EN ISO 181 EN ISO 236	13-2:2011;

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15.02.2022 Date

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Vitrotest ELISA kits & components

Vitrotest Borrelia IgG

Test immunoenzymatyczny do jakościowego i półilościowego wykrywania przeciwciał klasy IgG przeciwko Borrelia burgdorferi sensu lato

ELISA test kit for the qualitative and semiquantitative determination of IgG cla intibodies to Borrelia burgdorferi sensu /

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Vitrotest Europe Sp. z o.o. is Polish manufacturer of medical enzyme-linked immunosorbent assays for in vitro diagnostics. Our products contain a significant intellectual and innovative component.

ELISA KITS FOR INFECTIOUS DISEASES TESTING

- the analysis time is standardized for most kits
 - all kits contain microplates with easily detachable wells
 - clear and precise colored solutions facilitate analysis and reduce inaccuracy
 - interchangeable TMB,
 Washing and STOP solutions for all Vitrotest kits
 - unique positive and cut-off controls are synthesized according to the original technique

 absence of human origin components makes the use of kits safer

• the kits are verified on commercial panels of sera

 diagnostic characteristics of tests are comparable with the kits of leaders in the IVD industry

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 www.vitrotest.pl
 info@vitrotest.pl

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Helminthiasis

	Helminthiasis
EL051-96	Vitrotest Ascaris lumbricoides IgG ELISA test kit for the detection of IgG class antibodies to Ascaris lumbricoides
EL066-96	Vitrotest Echinococcus granulosus IgG ELISA test kit for the detection of IgG class antibodies to <i>Echinococcus granulosus</i>
EL058-96	Vitrotest Toxocara canis IgG ELISA test kit for the detection of IgG class antibodies to <i>Toxocara canis</i>
EL067-96	Vitrotest Trichinella spiralis IgG ELISA test kit for the detection of IgG class antibodies to <i>Trichinella spiralis</i>
	Borreliosis
EL084-96	Vitrotest Borrelia IgG ELISA test kit for the qualitative and semiquantitative determination of IgG class antibodies to <i>Borrelia burgdorferi sensu lato</i>
EL085-96	Vitrotest Borrelia IgM ELISA test kit for the qualitative and semiquantitative determination of IgM class antibodies to <i>Borrelia burgdorferi sensu lato</i>
	COVID-19
EL039-96	Vitrotest SARS-CoV-2 IgG ELISA test kit for the qualitative and semiquantitative determination of IgG class antibodies to coronavirus SARS-CoV-2
EL034-96	Vitrotest SARS-CoV-2 IgM ELISA test kit for the qualitative determination of IgM class antibodies to coronavirus SARS-CoV-2
EL038-96	Vitrotest SARS-CoV-2 Total Ab ELISA test kit for the qualitative determination of total antibodies to coronavirus SARS-CoV-2
EL040-96	Vitrotest SARS-CoV-2 IgG QuantiSpike ELISA test kit for the quantitative determination of IgG class antibodies to coronavirus SARS-CoV-2 Spike protein
	Helicobacter pylori infection
EL098-96	Vitrotest Helicobacter pylori IgG ELISA test kit for the qualitative and semiquantitative determination of IgG class antibodies to <i>Helicobacter pylori</i>
EL099-96	Vitrotest Helicobacter pylori IgA ELISA test kit for the qualitative and semiquantitative determination of IgA class antibodies to <i>Helicobacter pylori</i>
EL046-96	Vitrotest Helicobacter pylori CagA IgG ELISA test kit for the quantitative and semiquantitative determination of IgG class antibodies to CagA protein of <i>Helicobacter pylori</i>
EL047-96	Vitrotest Helicobacter pylori CagA IgA ELISA test kit for the qualitative and semiquantitative determination of IgA class antibodies to CagA protein of <i>Helicobacter pylori</i>
	Epstain-Barr Virus infection
EL053-96	Vitrotest EBV VCA IgG ELISA test kit for the qualitative and semiquantitative determination of IgG class antibodies to capsic antigen of Epstein-Barr Virus
EL052-96	Vitrotest EBV VCA IgM ELISA test kit for the qualitative and semiquantitative determination of IgM class antibodies to capsic antigen of Epstein-Barr Virus
EL054-96	Vitrotest EBV EBNA-1 IgG ELISA test kit for the qualitative and semiquantitative determination of IgG class antibodies to nuclea antigen of Epstein-Barr Virus
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