Vitrotest ELISA kits & components	EC DECLARATION OF CONFORMITY		
	No DoC_Ascaris_lumbricoides_IgG_EL051-96	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 Ascaris lumbricoides IgG** ELISA test kit for the detection of IgG class antibodies to *Ascaris lumbricoides*
PRODUCT CATALOGUE 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, 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.

This Declaration of conformity is issued under the responsibility of the manufacturer.

Edition 1

Wroclaw, Poland
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

Galyna Rayevska, Ph.D.
Chief of the Board

Digitally signed by Monastîrschii Viorica
Date: 2022.12.21 11:04:15 EET
Reason: MoldSign Signature
Location: Moldova

Vitrotest ELISA kits & components	EC DECLARATION OF CONFORMITY		
	No DoC_Borrelia_IgG_EL084-96	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 IgG** ELISA test kit for the qualitative and semiquantitative determination of IgG class antibodies to *Borrelia burgdorferi sensu lato*
PRODUCT CATALOGUE 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, 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.

This Declaration of conformity is issued under the responsibility of the manufacturer.

Edition 1

Wroclaw, Poland
Issued in

21.02.2022
Date

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

Galyna Rayevska, Ph.D.
Chief of the Board

Vitrotest ELISA kits & components	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 *Borrelia burgdorferi sensu lato*
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.

This Declaration of conformity is issued under the responsibility of the manufacturer.

Edition 1

Wroclaw, Poland
Issued in

21.02.2022
Date

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

Galyna Rayevska, Ph.D.
Chief of the Board

Vitrotest ELISA kits & components	EC DECLARATION OF CONFORMITY		
	No DoC_Helicobacter_pylori_IgA_EL099-96	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 Helicobacter pylori IgA** ELISA test kit for the qualitative and semiquantitative determination of IgA class antibodies to *Helicobacter pylori*
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 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.

This Declaration of conformity is issued under the responsibility of the manufacturer.

Edition 1

Wroclaw, Poland
Issued in

25.02.2022
Date

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

Galyna Rayevska, Ph.D.
Chief of the Board

Vitrotest ELISA kits & components	EC DECLARATION OF CONFORMITY		
	No DoC_Helicobacter_pylori_IgG_EL098-96	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 Helicobacter pylori IgG** ELISA test kit for the qualitative and semiquantitative determination of IgG class antibodies to *Helicobacter pylori*
PRODUCT CATALOGUE 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, 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.

This Declaration of conformity is issued under the responsibility of the manufacturer.

Edition 1

Wroclaw, Poland
Issued in

25.02.2022
Date

Galyna Rayevska

Galyna Rayevska, Ph.D.
Chief of the Board

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

Vitrotest ELISA kits & components	EC DECLARATION OF CONFORMITY		
	No DoC_Toxocara_canis_IgG_EL058-96	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 Toxocara canis IgG** ELISA test kit for the detection of IgG class antibodies to *Toxocara canis*
PRODUCT CATALOGUE 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 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.

This Declaration of conformity is issued under the responsibility of the manufacturer.

Edition 1

Wroclaw, Poland
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

Galyna Rayevska, Ph.D.
Chief of the Board

Vitrotest

ELISA kits & components

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

Vitrotest Europe Sp. z o.o.
Krakowska street 139-155,
Wroclaw, 50-428, Poland

+48 882 950 379
www.vitrotest.pl
info@vitrotest.pl

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 *Echinococcus granulosus*
EL058-96	**Vitrotest Toxocara canis IgG** ELISA test kit for the detection of IgG class antibodies to *Toxocara canis*
EL067-96	**Vitrotest Trichinella spiralis IgG** ELISA test kit for the detection of IgG class antibodies to *Trichinella spiralis*

Borreliosis

EL084-96	**Vitrotest Borrelia IgG** ELISA test kit for the qualitative and semiquantitative determination of IgG class antibodies to *Borrelia burgdorferi sensu lato*
EL085-96	**Vitrotest Borrelia IgM** ELISA test kit for the qualitative and semiquantitative determination of IgM class antibodies to *Borrelia burgdorferi sensu lato*

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 *Helicobacter pylori*
EL099-96	**Vitrotest Helicobacter pylori IgA** ELISA test kit for the qualitative and semiquantitative determination of IgA class antibodies to *Helicobacter pylori*
EL046-96	**Vitrotest Helicobacter pylori CagA IgG** ELISA test kit for the quantitative and semiquantitative determination of IgG class antibodies to CagA protein of *Helicobacter pylori*
EL047-96	**Vitrotest Helicobacter pylori CagA IgA** ELISA test kit for the qualitative and semiquantitative determination of IgA class antibodies to CagA protein of *Helicobacter pylori*

Epstain-Barr Virus infection

EL053-96	**Vitrotest EBV VCA IgG** ELISA test kit for the qualitative and semiquantitative determination of IgG class antibodies to capsid 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 capsid 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 nuclear antigen of Epstein-Barr Virus

Vitrotest Europe Sp. z o.o.
Krakowska street 139-155,
Wroclaw, 50-428, Poland

+48 882 950 379
www.vitrotest.pl
info@vitrotest.pl