| 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; |
| This Declaration of | conformity is issued u | nder the responsibility of t | he manufactu | ·er. |
| 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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| 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

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| 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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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

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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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 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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