



СЕРТИФІКАТ

CERTIFICATE * CERTIFICAT * ZERTIFIKAT * СЕРТИФИКАТ * CERTIFICADO

ОРГАН СЕРТИФІКАЦІЇ СИСТЕМ УПРАВЛІННЯ
ДП «УКРМЕТРТЕСТСТАНДАРТ»
ЗАСВІДЧУЄ, ЩО

СИСТЕМА УПРАВЛІННЯ ЯКІСТЮ

ТОВАРИСТВА З ОБМЕЖЕНОЮ ВІДПОВІДАЛЬНІСТЮ «ВІТРОТЕСТ БІОРЕАГЕНТ»

Юридична адреса: вул. Бойчука, 18-Б, кв. 56, м. Київ,
01103, Україна
Адреса виробництва: вул. Курортна, 11, м. Київ, 04075, Україна

код ЄДРПОУ 42149820

СТОСОВНО
розроблення та виробництва тест-систем імуноферментних

**ВІДПОВІДАЄ ВИМОГАМ
ДСТУ EN ISO 13485:2018
(EN ISO 13485:2016, IDT; ISO 13485:2016, IDT)**

Сертифікат № UA.C.378–19 в Реєстрі Органу сертифікації
zareєстрований " 25 " листопада 2019 року
чинний до " 24 " листопада 2022 року

Заступник керівника
Органу сертифікації



В.Д. Ример



ДЕРЖАВНЕ ПІДПРИЄМСТВО «ВСЬУКРАЇНСЬКИЙ ДЕРЖАВНИЙ НАУКОВО-ВИРОБНИЧИЙ ЦЕНТР
СТАНДАРТИЗАЦІЇ, МЕТРОЛОГІЇ, СЕРТИФІКАЦІЇ ТА ЗАХИСТУ ПРАВ СПОЖИВАЧІВ»
(ДП «УКРМЕТРТЕСТСТАНДАРТ»)

вул. Метрологічна, 4, м. Київ, 03143, Україна, тел./факс +38 044 452-67-38
Атестат акредитації НААУ № 80020

№ 80020
ДСТУ EN ISO/IEC 17021-1

Чинність сертифікату можна перевірити на сайті www.certsystems.kiev.ua в розділі
«Послуги / Сертифікація систем управління»

DECLARATION OF CONFORMITY №UA-TK051

Manufacturer: Vitrotest Bioreagent LLC
State registration № 42149820

Legal address: M.Boychuka 18b, of.56, Kyiv 01103 Ukraine
Manufacturer's address: Kurortnaya 11, Kyiv, 04075, Ukraine

Description of the product:

Name	Catalog Number
ELISA test-kit for the determination of antibodies to <i>Ascaris lumbricoides</i> «Vitrotest Anti-Ascaris»	TK051

Classification:
According to medical devices technical regulation for *in vitro* diagnostics, approved by Cabinet of Ministers decree from 02.10.2013 №754

Is not a part of A and B lists, is not a device for self-testing, not for performance assessment.

Conformity assessment procedure: Annex 3 of medical devices technical regulation for *in vitro* diagnostics, approved by Cabinet of Ministers decree from 02.10.2013 №754

Vitrotest Bioreagent declares the execution of all demands regarding the device, that was mentioned above, according to medical devices technical regulation for *in vitro* diagnostics, approved by Cabinet of Ministers decree from 02.10.2013 №754, and the requirements of further regulations:

ДСТУ EN ISO 13485:2018
ДСТУ EN ISO 14971:2015
ДСТУ EN 13641:2015
ДСТУ EN ISO 15223-1:2018 (EN ISO 15223-1:2016, IDT; ISO 15223-1:2016, Corrected version 2017-03, IDT)
ДСТУ EN ISO 23640:2015 (EN ISO 23640:2015, IDT; ISO 23640:2011, IDT)

The declaration is made under sole responsibility of the manufacturer.

Date of issue: 31.10.2019
Validity of declaration till: 31.10.2024

Director



Ihor Nikolaienko, Ph.D.

DECLARATION OF CONFORMITY №UA-TK030

Manufacturer: Vitrotest Bioreagent LLC
State registration № 42149820

Legal address: M.Boychuka 18b, of.56, Kyiv 01103 Ukraine
Manufacturer's address: Kurortnaya 11, Kyiv, 04075, Ukraine

Description of the product:

Name	Catalog Number
ELISA test-kit for the determination of antibodies to <i>Giardia lamblia</i> (<i>intestinalis</i>) «Vitrotest Anti-Lamblia»	TK030

Classification:
According to medical devices technical regulation for *in vitro* diagnostics, approved by Cabinet of Ministers decree from 02.10.2013 №754

Is not a part of A and B lists, is not a device for self-testing, not for performance assessment.

Conformity assessment procedure: Annex 3 of medical devices technical regulation for *in vitro* diagnostics, approved by Cabinet of Ministers decree from 02.10.2013 №754

Vitrotest Bioreagent declares the execution of all demands regarding the device, that was mentioned above, according to medical devices technical regulation for *in vitro* diagnostics, approved by Cabinet of Ministers decree from 02.10.2013 №754, and the requirements of further regulations:

ДСТУ EN ISO 13485:2018
ДСТУ EN ISO 14971:2015
ДСТУ EN 13641:2015
ДСТУ EN ISO 15223-1:2018 (EN ISO 15223-1:2016, IDT; ISO 15223-1:2016, Corrected version 2017-03, IDT)
ДСТУ EN ISO 23640:2015 (EN ISO 23640:2015, IDT; ISO 23640:2011, IDT)

The declaration is made under sole responsibility of the manufacturer.

Date of issue: 31.10.2019
Validity of declaration till: 31.10.2024

Director



Ihor Nikolaienko, Ph.D.

DECLARATION OF CONFORMITY №UA-TK058

Manufacturer: Vitrotest Bioreagent LLC
State registration № 42149820

Legal address: M.Boychuka 18b, of.56, Kyiv 01103 Ukraine
Manufacturer's address: Kurortnaya 11, Kyiv, 04075, Ukraine

Description of the product:

Name	Catalog Number
ELISA test-kit for the determination of antibodies to <i>Toxocara canis</i> «Vitrotest Anti-Toxocara»	TK058

Classification:
According to medical devices technical regulation for *in vitro* diagnostics, approved by Cabinet of Ministers decree from 02.10.2013 №754

Is not a part of A and B lists, is not a device for self-testing, not for performance assessment.

Conformity assessment procedure: Annex 3 of medical devices technical regulation for *in vitro* diagnostics, approved by Cabinet of Ministers decree from 02.10.2013 №754

Vitrotest Bioreagent declares the execution of all demands regarding the device, that was mentioned above, according to medical devices technical regulation for *in vitro* diagnostics, approved by Cabinet of Ministers decree from 02.10.2013 №754, and the requirements of further regulations:

ДСТУ EN ISO 13485:2018

ДСТУ EN ISO 14971:2015

ДСТУ EN 13641:2015

ДСТУ EN ISO 15223-1:2018 (EN ISO 15223-1:2016, IDT; ISO 15223-1:2016, Corrected version 2017-03, IDT)

ДСТУ EN ISO 23640:2015 (EN ISO 23640:2015, IDT; ISO 23640:2011, IDT)

The declaration is made under sole responsibility of the manufacturer.

Date of issue: 31.10.2019

Validity of declaration till: 31.10.2024

Director



Ihor Nikolaienko, Ph.D.

DECLARATION OF CONFORMITY №UA-TK039

Manufacturer: Vitrotest Bioreagent LLC
State registration № 42149820

Legal address: M.Boychuka 18b, of.56, Kyiv 01103 Ukraine
Manufacturer's address: Kurortnaya 11, Kyiv, 04075, Ukraine

Description of the product:

Name	Catalog Number
ELISA test-kit for the qualitative and semiquantitative determination of IgG antibodies to SARS-CoV-2 «Vitrotest SARS-CoV-2 IgG»	TK039

Classification:

According to medical devices technical regulation for *in vitro* diagnostics, approved by Cabinet of Ministers decree from 02.10.2013 №754

Is not a part of A and B lists, is not a device for self-testing, not for performance assessment.

Conformity assessment procedure:

Annex 3 of medical devices technical regulation for *in vitro* diagnostics, approved by Cabinet of Ministers decree from 02.10.2013 №754

Vitrotest Bioreagent declares the execution of all demands regarding the device, that was mentioned above, according to medical devices technical regulation for *in vitro* diagnostics, approved by Cabinet of Ministers decree from 02.10.2013 №754, and the requirements of further regulations:

ДСТУ EN ISO 13485:2018
ДСТУ EN ISO 14971:2015
ДСТУ EN 13641:2015
ДСТУ EN ISO 15223-1:2018 (EN ISO 15223-1:2016, IDT; ISO 15223-1:2016, Corrected version 2017-03, IDT)
ДСТУ EN ISO 23640:2015 (EN ISO 23640:2015, IDT; ISO 23640:2011, IDT)
ДСТУ EN 13612:2015
ДСТУ EN ISO 18113-1:2018 (EN ISO 18113-1:2011, IDT; ISO 18113-1:2009, IDT)
ДСТУ EN ISO 18113-2:2018 (EN ISO 18113-2:2011, IDT; ISO 18113-2:2009, IDT)
ДСТУ EN 980:2007

The declaration is made under sole responsibility of the manufacturer.

Date of issue: 17.04.2020

Validity of declaration till: 17.04.2025

Director


(signature)

Ihor Nikolaienko, Ph.D.
(ПІП)

Edition 1 from 17.04.2020



DECLARATION OF CONFORMITY №UA-TK033

Manufacturer: Vitrotest Bioreagent LLC
State registration № 42149820

Legal address: M.Boychuka 18b, of.56, Kyiv 01103 Ukraine

Manufacturer's address: Kurortnaya 11, Kyiv, 04075, Ukraine

Description of the product:

Name	Catalog Number
ELISA test-kit for the qualitative and semiquantitative determination of IgA antibodies to SARS-CoV-2 «Vitrotest SARS-CoV-2 IgA»	TK033
ELISA test-kit for the qualitative determination of IgM antibodies to SARS-CoV-2 «Vitrotest SARS-CoV-2 IgM»	TK034, TK042

Classification:

According to medical devices technical regulation for *in vitro* diagnostics, approved by Cabinet of Ministers decree from 02.10.2013 №754

Is not a part of A and B lists, is not a device for self-testing, not for performance assessment.

Conformity assessment procedure:

Annex 3 of medical devices technical regulation for *in vitro* diagnostics, approved by Cabinet of Ministers decree from 02.10.2013 №754

Vitrotest Bioreagent declares the execution of all demands regarding the device, that was mentioned above, according to medical devices technical regulation for *in vitro* diagnostics, approved by Cabinet of Ministers decree from 02.10.2013 №754, and the requirements of further regulations:

ДСТУ EN ISO 13485:2018
ДСТУ EN ISO 14971:2015
ДСТУ EN 13641:2015
ДСТУ EN ISO 15223-1:2018 (EN ISO 15223-1:2016, IDT; ISO 15223-1:2016, Corrected version 2017-03, IDT)
ДСТУ EN ISO 23640:2015 (EN ISO 23640:2015, IDT; ISO 23640:2011, IDT)
ДСТУ EN 13612:2015
ДСТУ EN ISO 18113-1:2018 (EN ISO 18113-1:2011, IDT; ISO 18113-1:2009, IDT)
ДСТУ EN ISO 18113-2:2018 (EN ISO 18113-2:2011, IDT; ISO 18113-2:2009, IDT)
ДСТУ EN 980:2007

The declaration is made under sole responsibility of the manufacturer.

Date of issue: 20.11.2020

Validity of declaration till: 20.11.2025

Director



Ihor Nikolaienko, Ph.D.
(п.п.п.)

DECLARATION OF CONFORMITY №UA-TK040

Manufacturer: Vitrotest Bioreagent LLC
State registration № 42149820

Legal address: M.Boychuka 18b, of.56, Kyiv 01103 Ukraine
Manufacturer's address: Kurortnaya 11, Kyiv, 04075, Ukraine

Description of the product:

Name	Catalog Number
ELISA test-kit for quantitative determination of IgG antibodies to SARS-CoV-2 spike protein «Vitrotest SARS-CoV-2 IgG QuantiSpike»	TK040

Classification:

According to medical devices technical regulation for *in vitro* diagnostics, approved by Cabinet of Ministers decree from 02.10.2013 №754

Is not a part of A and B lists, is not a device for self-testing, not for performance assessment.

Conformity assessment procedure:

Annex 3 of medical devices technical regulation for *in vitro* diagnostics, approved by Cabinet of Ministers decree from 02.10.2013 №754

Vitrotest Bioreagent declares the execution of all demands regarding the device, that was mentioned above, according to medical devices technical regulation for *in vitro* diagnostics, approved by Cabinet of Ministers decree from 02.10.2013 №754, and the requirements of further regulations:

ДСТУ EN ISO 13485:2018

ДСТУ EN ISO 14971:2015

ДСТУ EN 13641:2015

ДСТУ EN ISO 15223-1:2018 (EN ISO 15223-1:2016, IDT; ISO 15223-1:2016, Corrected version 2017-03, IDT)

ДСТУ EN ISO 23640:2015 (EN ISO 23640:2015, IDT; ISO 23640:2011, IDT)

ДСТУ EN 13612:2015

ДСТУ EN ISO 18113-1:2018 (EN ISO 18113-1:2011, IDT; ISO 18113-1:2009, IDT)

ДСТУ EN ISO 18113-2:2018 (EN ISO 18113-2:2011, IDT; ISO 18113-2:2009, IDT)

ДСТУ EN 980:2007

The declaration is made under sole responsibility of the manufacturer.

Date of issue: 15.03.2021

Validity of declaration till: 15.03.2026

Director



(signature)

Ihor Nikolaienko, Ph.D.
(ПІП)

Edition 1 from 15.03.2021



№ 06/22

Date: 19.01.2022 p.

STATEMENT

We, Vitrotest Bioreagent LLC, having a registered office at M. Boychuka street 18b/56, Kyiv 01103 Ukraine, assign SRL SANMEDICO having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as authorized representative.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Signature: _____



Director Ihor Nikolaienko Ph.D

