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

Digitally signed by Monastîrschii Viorica
Date: 2023.01.24 13:30:32 EET
Reason: MoldSign Signature
Location: Moldova

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.

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тел:+48 882 950 379
info@vitrotest.pl
NIP: 8992881308

Wrocław, 02.06.2022

To whom it may concern

STATEMENT

Herewith we, Vitrotest Europe Sp. z O.O. with registered address at Krakowska str., 139-155, 50-428, Wroclaw, Poland, acting as a manufacturer, hereby assign SRL SANMEDICO having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova , as authorized representative in Republic Moldova.

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.

June 2, 2022

Galyna Rayevska, Chief of the board

Vitrotest Europe Sp. z O.O.

Vitrotest Europe Sp. z o.o.
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