

MANUFACTURER: **Vitrotest Europe Sp. z O.O.**

ADDRESS: **Krakowska str., 139-155, 50-428, Wrocław, Poland**

PRODUCT NAME: **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

PRODUCT CATALOGUE NUMBER: **EL054-96**

GMDN CODE: **49657**

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

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

Edition 1

Wrocław, Poland

23.02.2022

Issued in

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

