EU declaration of conformity

in vitro diagnostic medical device

Registration number:
LT/CA01/IVD/003/20

Manufacturer: UAB "YZZY biotech"
Address: Beržų str. 8, LT-36233 Panevėžys, LITHUANIA

At our own risk, WE DECLARE that the device:

Medical device: YZZY Test COVID-19
Model: Real-Time PCR reagents kit - YZZY Test COVID-19
Class: Other (IVD medical device (device) for professional use)

Description of the medical device:
"YZZY Test COVID-19 PCR reagent kit" is a kit for the identification of the coronavirus SARS-CoV-2 RNA infectious disease COVID-19. The isolated RNA reacts with the YZZY Test COVID-19 PCR Reagent Kit in real time.

Complies with relevant Union harmonization legislation: Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

The declaration of conformity is based on Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices Annex III.

The manufacturer ensures that:

- The production process is organized in accordance with the requirements of the Quality Management System ISO 9001:2015.
- technical documentation is prepared and maintained in accordance with Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

Place: Panevėžys Lithuania
Issued date: 2020-08-24
Director Tomas Vaitkevičius
Signature: