EU declaration of conformity

in vitro diagnostic medical device

IVD Registration number:
LT/CA01/IVD/004/21

CE

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

Description of the medical device:
"YZZY Test Covid-19 Express" kit intended for the FAST qualitative detection of SARS-CoV-2 virus RNA by one-step RT-PCR assay with Real-Time detection without (or after) isolation of RNA.

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.

JSC "YZZY biotech"