

EU declaration of conformity

in vitro diagnostic molecular reagents



Manufacturer: UAB "YZZY biotech"

Address: Beržų str. 8, LT-36233 Panevėžys, LITHUANIA

At our own risk, WE DECLARE that the device:

Model: YZZY 5X One-Step RT-PCR Mastermix

Class: Other (IVD medical device (device) for professional use)

Description of the medical device: YZZY 5X One-Step RT-PCR Mastermix is a ready-to-use universal reagent for the synthesis of cDNA on RNA matrix with the following polymerase chain reaction with real time identification of products (RT-PCR).

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"