

## 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 RevM Hot Start Revertase

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

**Description of the medical device:** YZZY RevM Hot Start Revertase is a genetically modified reverse transcriptase of Moloney Mouse Leukemia Virus (MMLV), is intended for the synthesis of a complementary DNA strand (cDNA) on a single-stranded RNA template.

**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"