



DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: SHANGHAI ZJ BIO-TECH CO., LTD

Address: 1st Floor, Gate B, Building #20 & 1st Floor, Gate A, Building #21, 528 Ruiqing Road, Zhangjiang High-Tech Industrial East District, Shanghai, China.

European Representative: Riomavix S.L.

Address: Calle de Almansa 55, 1D, Madrid 28039 Spain

In Vitro Diagnostic:

- Monkeypox Virus Real Time PCR Kit

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III

Applicable Standards:

EN ISO 13485:2016/AC:2018/A11:2021 *EN ISO 18113-2:2011* *EN 13612:2002/AC:2002*
ISO 14971:2019 *EN ISO 23640:2015* *EN ISO 15223-1:2021*
EN ISO 18113-1:2011 *EN 62366-1:2015/A1:2020*

We, the manufacturer, herewith declare with sole responsibility that our products mentioned above meet the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on *Mei Wu*

Date: May 20th, 2022

Place: Shanghai, China

Name of authorized signatory: Mei Wu

Position held in the company: PRRC

Seal Stamp:

SHANGHAI ZJ BIO-TECH CO., LTD

