CE 2934

DECLARATION OF CONFORMITY

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

Manufacturer: Lansion Biotechnology Co.,Ltd.

Address: No.2, Qiande Road, Science Park, Jiangning District, 210000 Nanjing, Jiangsu Province, P.R. China

Authorized representative: Lotus NL B.V.

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Notified body: CeCert Sp. z o.o.

Identification Number: 2934

In Vitro Diagnostic Directive:

- COVID-19 Antigen Test Kit For Saliva (Dry Color Latex Immunoassay)

REF: 0902-01, 0902-03, 0902-05, 0902-06, 0902-07

Risk Class: IVD for self-testing (In accordance with the rule set out in Annex III of DIRECTIVE 98/79/EC)

Conformity assessment route: Declaration of Conformity IVDD Annex III, point 6.

Applicable Standards:

EN ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
EN ISO 14971:2012	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011	*ISO 14971:2019*	

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s 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:

Place: Nanjing, China

Name of authorized signatory: Bingbing Zhao

Position held in the company:

Enterprise management Representative

Date: 2022.05.16

Seal/Stamp:

Lansion Biotechnology Co.,Ltd.