



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, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

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

In Vitro Diagnostic Directive:

- LS-4000 Dry Fluorescence Immunoassay Analyzer (Handheld)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

<i>ISO 13485:2016</i>	<i>EN ISO 18113-3:2011</i>	<i>EN 13612:2002</i>
<i>ISO 14971:2019</i>	<i>EN 13641:2002</i>	<i>ISO 23640:2015</i>
<i>EN ISO 18113-1:2011</i>	<i>ISO 15223-1:2016</i>	<i>EN 62366-1:2015</i>
<i>EN ISO 18113-2:2011</i>		

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:

Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

