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Digitally signed by Matei Andrei
Date: 2022.07.15 14:07:30 MSK
Reason: MoldSign Signature
Location: Moldova

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:

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

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.

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 002596 0002 Rev. 01

Holder of Certificate: **Lansion Biotechnology Co., Ltd.**
No.2 Qiande Road, Science Park, Jiangning District
210000 Nanjing, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Lansion Biotechnology Co., Ltd.
No.2 Qiande Road, Science Park, Jiangning District, 210000 Nanjing, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate.

Certification Mark:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of Dry Fluorescence Immunoassay Analyzer, Dry Fluorescence Immunoassay test kit, Coagulation Test Kit(Electrochemistry), Handheld coagulation Analyzer**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 002596 0002 Rev. 01

Report No.: SH20126602
Valid from: 2021-04-12
Valid until: 2024-04-02

Date, 2021-04-12

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Lansion Biotechnology Co., Ltd.
No.5 Qiande Road, Jiangning District, Nanjing，China

Declaration

Monday 7th February 2022

To whom it may concern:

We are Lansion Biotechnology.,Ltd. Localed at No.5 Qiande Road, Jiangning District, Nanjing，China.Hereby declare ：

We are the official manufacturers of the handheld Dry Fluorescence Immunassay Analyzer LS-4000, declare that the aforementioned model can be installed and used in the auto-ambulance.

Lansion Biotechnology.,Ltd.
Area manager:
Signature:
Date:13/07/2022

南京岚煜生物科技有限公司
Lansion Biotechnology Co., Ltd.