



EC Certificate

Full Quality Assurance System Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6) (List A and B and devices for self-testing)

No. V1 101151 0002 Rev. 00

Hangzhou Lysun Biotechnology Co., Ltd. Manufacturer:

> 6th Floor, 6th Building No. 95 Binwen Road

Xixing Street **Binjiang District**

310051 Hangzhou, Zhejiang PEOPLE'S REPUBLIC OF CHINA

Lotus NL B.V. **EC-Representative:**

Koningin Julianaplein 10, 1e Verd, 2595AA The Hague, THE

NETHERLANDS

Product Category(ies): In Vitro diagnostic devices for self testing

Blood Glucose, Uric Acid and Blood lipid

self-testing system

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. See also notes overleaf.

SH18141101 Report no.:

2019-08-05 Valid from: Valid until: 2024-05-26

2019-08-05 Date,

Stefan Preiß

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Model(s): Blood Glucose Meter(BGM- Series), Blood Glucose Test

Strip and control solution(EGS-Series), Multifunction Analysis Meter(Glucose, Uric Acid)(GUM- Series), Uric Acid Test Strip and control solution(EUS-Series), Blood Lipid Analysis Meter(LPM- Series), Blood Lipid Test Strip(LPS- Series), Blood Lipid control solution(TCS-

Series, LPS-Series)

Facility(ies): Hangzhou Lysun Biotechnology Co., Ltd.

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