DECLARATION OF CONFORMITY

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

Manufacturer: Hangzhou Lysun Biotechnology Co., Ltd.
Address: 6th Floor, 6th Building, No.95 Binwen Road, Xixing Street, Binjiang District, 310051 Hangzhou, Zhejiang, China
European Representative： Lotus NL B.V.
Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands

Medical Devices：

- Dry Biochemical Analysis Meter（DBM- 101）
- Total Cholesterol Test Strip（Dry Chemistry）（TCS-101）
- High-density Lipoprotein Test Strip（Dry Chemistry）（HLS-101）
- Triglycerides Test Strip（Dry Chemistry）（TGS-101）
- Renal Function Test Strip（Dry Chemistry）（RFS-101）
- Uric Acid Test Strip（Dry Chemistry）（UAS-101）
- Creatinine Test Strip（Dry Chemistry）（CRS-101/CRS-102）
- Urea Test Strip（Dry Chemistry）（URS-101）
- Blood Lipid Analysis Meter （LPM-101/LPM-102）
- Blood Lipid Test Strip（LPS-101）
- Renal Function Analysis Meter（RFM-101/RFM-201/RFM-202）
- Blood Glucose Meter（BGM-101/BGM-102/BGM-103）
- Blood Glucose Test Strip（EGS-101）
- Multifunction Analysis Meter（Glucose&Uric Acid）（GUM-101）
- Uric Acid Test Strip（Electrochemistry）（EUS-101）
- Hemoglobin Analysis Meter（BHM-101/BHM-102/BHM-202）
- Hemoglobin Test Strip（Dry Chemistry）（BHS-101/BHS-201）

- Multifunction Analysis Meter(GULP-101/GULP-102)
- Blood Glucose Control Solution(EGS-A/EGS-B/EGS-C)
- Uric Acid Control Solution（Electrochemistry）(EUS-A/EUS-B/EUS-C)

Category： Other Devices

Conformity assessment route： Declaration of Conformity IVDD Annex III

Applicable Standards:

EN ISO 13485:2016
EN ISO 14971:2019
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN 13975:2010
EN 17511:2003
EN ISO 15223-1:2016
EN 13612:2002/AC:2002
EN ISO 23640:2015
EN 62366:2008

We, the Manufacturer, herewith 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 has a certified Quality Management System in place based on the ISO 13485:2016 standard.This has been assessed by TÜV SÜD.

We agrees to develop,implement and maintian a documented post-production monitoring process.

Signed on 6th August 2019

Place Hangzhou, China

Name of authorized signatory: Chen Junfang

Position held in the company: General Manager

Seal/Stamp:

Hangzhou Lysun Biotechnology Co., Ltd.