# EC Certificate

TÜVRheinland®

**Full Quality Assurance System**
**Directive 98/79/EC on In Vitro Diagnostic Medical Devices,**
**Annex IV excluding (4, 6)**

Registration No.: HL 2062714-1

Manufacturer: BEIJING LEPU MEDICAL TECHNOLOGY CO.,LTD.
Building 7-1, No. 37,
Chaoqian Road, Changping District
102200 Beijing
P.R. China

Products: Blood Glucose Monitoring Systems
Blood Glucose Test Strips
SARS-CoV-2 Antigen Rapid Tests for self-testing



The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 190131772 110

Effective date: 2021-06-21

Expiry date: 2024-05-26

Issue date: 2021-06-21

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Dipl. Ing. Sven Hoffmann
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

TÜVRheinland®

# Certificate

**Quality Management System**
**EN ISO 13485:2016**

Registration No.: SX 2062714-1

Organization: BEIJING LEPU MEDICAL TECHNOLOGY CO., LTD.
Building 7-1, No. 37 Chaoqian Road, Changping District,
102200 Beijing, P. R. China

Scope: Design and Development, Manufacture, Distribution and Service of In-vitro Diagnostic Analyzers and In-vitro Diagnostic Test Kits used in Detection of Cardiac Markers, Blood Analytics, Genetic Testing, Disease Status, Infectious Disease, Cancer Markers and Blood Glucose Monitoring including Meters and Strips including Home Use

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 16805473 008

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Issue date: 2020-12-07

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

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