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

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.