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

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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.