

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

Effective date: 2020-12-06

Expiry date: 2022-02-12

Issue date: 2020-12-07



Wenxiang Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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Business Stream Products
Certification Department



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Building 7-1, No. 37 Chaoqian Road, Changping District,
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Contact

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Date: December 09, 2020

Application for: QMS

Certificate No. : SX 2062714-1

Requirement : EN ISO 13485:2016

Dear Madam or Sir,

Enclosed please find the new certificate No. SX 2062714-1 replacing the previous certificate.

With effective date of the new certificate, the previous certificate becomes invalid.

Best regards,

Wenxiang Zhang
Certification body

A handwritten signature in blue ink, appearing to read 'Zhang', is placed to the right of the printed name and title.