

Certificate

The Certification Body of TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

BEIJING LEPU MEDICAL TECHNOLOGY CO., LTD. Building 7-1 No.37 Chaogian Road Changping District 102200 Beijing China

has established and applies a quality management system for medical devices for the following scope:

(see attachment for scope)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:

2019-04-17

Certificate Registration No.:

SX 60135206 0001

An audit was performed. Report No.: 16805473 005

This Certificate is valid until:

2022-02-12

Certification Body



Date 2019-04-17



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TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg Doc. 1/1, Rev. 0

Attachment to Certificate

Registration No.:

SX 60135206 0001

Report No.:

16805473 005

Organization:

BEIJING LEPU MEDICAL TECHNOLOGY CO., LTD.

Building 7-1

No.37 Chaoqian Road Changping District 102200 Beijing

China

Scope:

Design and Development, Manufacture, Distribution and Service of in-vitro diagnostic analyzers and in-vitro diagnostic test kits used in the detection of Cardiac Markers, Blood Analytics, Genetic Testing and Blood Glucose Monitoring including meters and strips including Home Use

Certification Body



Date: 2019-04-17

