



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 Chaoqian 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

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com http://www.tuv.com/safety



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