

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Genrui Biotech Inc.
4-10F, Building 3
Geya Technology Park
Guangming District
518106 Shenzhen
China

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

(see attachment for scope included)

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: 2018-12-04
Certificate Registration No.: SX 60131228 0001
An audit was performed. Report No.: 17057612 005
This Certificate is valid until: 2021-10-12

Certification Body



Date 2018-12-04



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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60131228 0001
Report No.: 17057612 005

Organization: Genrui Biotech Inc.
4-10F, Building 3
Geya Technology Park
Guangming District
518106 Shenzhen
China

Scope:

Design and Development, Manufacture and Distribution of Biochemistry-, Electrolyte-, Hematology-, Urine-, Coagulation-, Specific Protein-, Quantitative Immunoassay-, and Chemiluminescence Immunoassay Analyzers; Reagents for Biochemistry-, Electrolyte-, Hematology-, Urine-, Specific Protein- and Quantitative Immunoassay Analyzers

Certification Body



Date: 2018-12-04

