

**REGISTRATION NO. 04719Q10000163** 

## CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

Genrui Biotech Inc.

Registered Address: 4-10F, Building 3, Geya Technology Park, Guangming District, 518106, Shenzhen, P.R.China

Manufacturing Address: 4-10F, Building 3, Geya Technology Park, Guangming District, 518106, Shenzhen, P.R.China

Has been assessed and conformed to the following standard(s)
YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope:

The Design, Development, Producion and Service of in vitro diagnostic reagents (see annex) and the Analyzers which cover Auto Hematology Analyzer, Coagulation Analyzer, Semi-auto Chemistry Analyzer, Auto Chemistry Analyzer, Specific Protein Analyzer, Electrolyte Analyzer, Fully Auto Specific Protein Analyzer, Quantitative Immunofluorescence Analyzer, 5-part Auto Hematology Analyzer, Chemiluminescence Immunoassay Analyzer, Fully-Auto Nucleic Acid Extraction analyzer.

Date of issue: December 16,2019
Date of expiry: December 15,2022
Date of change: December 24,2020

General Manager:

BEIJING HUA GUANG CERTIFICATION OF MEDICAL DEVICES CO., LTD.