



Certificate

No. Q5 054903 0001 Rev. 00

Holder of Certificate: **Labnovation Technologies, Inc.**

101 and 5th Floor, Building 1, No. 68
18th Road, Guangming Hi-Tech Park
Tangjia Community, Fenghuang Street
Guangming District
518107 Shenzhen, Guangdong
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Labnovation Technologies, Inc.
101 and 5th Floor, Building 1, No. 68, 18th Road, Guangming Hi-
Tech Park, Tangjia Community, Fenghuang Street, Guangming
District, 518107 Shenzhen, Guangdong, PEOPLE'S REPUBLIC
OF CHINA

Certification Mark:



Scope of Certificate:

Design and Development, Production and Distribution of Reagents for Hematology Analyzers; Reagents, Quality Controls and Calibrators for Biochemistry Analyzers; Immunoturbidimetry Reagents; Immunochromatography Assay Kits; Electrolyte Reagents; Reagents for Urine Sediment Analyzers; Reagents Kit, Calibrators and Quality Controls for Glycated Hemoglobin Analyzers; Glycated Hemoglobin Analyzers; Immunochromatography Analyzers

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: GZ2044401

Valid from: 2020-08-07

Valid until: 2023-08-06

Date, 2020-08-07

Christoph Dicks
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT