TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

General Life Biotechnology Co., Ltd.
5F, No. 240, Shinshu Rd.,
Shin Juang Dist.,
New Taipei City 242
Taiwan

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

(see attachment for scope and additional site 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:	2018-04-26
Certificate Registration No.:	SX 60128112 0001
An audit was performed. Report No.:	50117085 001
This Certificate is valid until:	2021-04-06

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Digitally signed by Ceaicovschi Tudor
Date: 2021.02.25 10:38:22 EET
Reason: MoldSign Signature
Location: Moldova

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2018-04-26

X. Ren

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60128112 0001
Report No.: 50117085 001

Organization:
General Life Biotechnology Co., Ltd.
5F, No. 240, Shinshu Rd.,
Shin Juang Dist.,
New Taipei City 242
Taiwan

Scope:

Design and Development, Manufacture and Distribution of in vitro diagnostic clinical chemical medical devices used in monitoring of blood glucose and blood analytes, including self-testing and near patient/point of care.

Site included:

General Life Biotechnology Co., Ltd.
6F, No. 272-1, Shinshu Rd.
Shin Juang Dist., New Taipei City 242
Taiwan

Design and Development of in vitro diagnostic clinical chemical medical devices (meter) used in monitoring of blood glucose and blood analytes, including self-testing and near patient/point of care.
Distribution of in vitro diagnostic clinical chemical medical devices used in monitoring of blood glucose and blood analytes, including self-testing and near patient/point of care.

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D-ZM-14169-01-02

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Date: 2018-04-26