

Certificate

**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 2100077-1

Organization: Apex Biotechnology Corp.
No. 7, Li-Hsin Road V
Hsinchu Science Park
Hsinchu
Taiwan

Scope: Design and development, manufacture and distribution of in-vitro diagnostic medical devices regarding to biochemistry including meters, test strips and control solution used in the monitoring of blood physiological analytes including self-testing and point of care in-vitro diagnostic devices.
Design and development, manufacture and distribution of in-vitro diagnostic medical devices regarding to immunoassay including analyzer and cartridge used in the monitoring of blood physiological analytes point of care in-vitro diagnostic devices.

TÜVRheinland

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 238512299-040
Effective date: 2021-09-29
Expiry date: 2024-09-28
Issue date: 2021-08-31



Dipl.-Ing. W. Hsu
TÜV Rheinland LGA Products GmbH
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The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Apex Biotechnology Corp. No. 180, Ln.70, Wuqing Rd., Dayuan Dist., Taoyuan City 337 Taiwan	Manufacture of Electrode Card

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