



America

CERTIFICATE

No. QS6 120783 0002 Rev. 00

Certificate Holder:

Apex Biotechnology Corp.

No. 7, Li-Hsin Road V
Hsinchu Science Park
30078 Hsinchu
TAIWAN

Certification Mark:



Scope of Certificate:

Design and Development, Manufacture, Distribution and Service of In-Vitro Diagnostic Instruments and Reagents (Meters, Test Strips, Control Solutions) for Clinical Chemistry used to Monitor Physiological Analytes in Blood including Self-Testing and Point of Care;

Design and Development, Manufacture, Distribution and Service of In-Vitro Diagnostic Instruments and Reagents (Analyzers, Cartridges, Control Solutions) for Immunochemistry used to Monitor Physiological Analytes in Blood and Urine including Point of Care

Standard(s):

ISO 13485:2016

Regulatory Authority(ies):

Brazil ANVISA, Health Canada, USA FDA. See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:QS6 120783 0002 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:QS6_120783_0002_Rev_00)

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID:

F006853

Report No.:

TW2310501

Effective Date:

2023-10-24

Expiry Date:

2026-10-23

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Date of Issue: 2023-11-21

(Renee Walker)
Director, US Certification Body, MHS



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Regulatory Requirements: Audit/Certification Criteria

Brazil

- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

Canada

- Medical Device Regulations – Part 1- SOR 98/282

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies):

Apex Biotechnology Corp.

No. 7, Li-Hsin Road V, Hsinchu Science Park, 30078 Hsinchu, TAIWAN

Apex Biotechnology Corp.

No.180, Ln.70, Wuqing Rd., Dayuan Dist., 33755 Taoyuan City, TAIWAN

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Manufacture of Electrode Card
REPs Facility ID: F006854

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