ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 120783 0001 Rev. 01

Holder of Certificate: **Apex Biotechnology Corp.**
No. 7, Li-Hsin Road V
Hsinchu Science Park
30078 Hsinchu
TAIWAN

Certification Mark:

Scope of Certificate:

Design and Development, Manufacturing and Distribution of in - vitro diagnostic instruments and reagents (meters, test strips, control solutions) for clinical chemistry used to monitor physiological parameters in blood (incl. self-testing / point of care), and for immunochemistry (analyzers, cartridges. control solutions) used to monitor physiological parameters in blood and urine (incl. point of care).

Servicing of in-vitro diagnostic instruments for clinical chemistry and Immunochemistry used to monitor physiological parameters in blood or urine (incl. self-testing / point of care).

Design and Development, Manufacturing and Distribution of in-vitro diagnostic reagents for infectious disease diagnosis (colloidal gold method).

The provision of Design and Development, Manufacturing, Warehousing and Distribution services for sterile non-active, non-implantable medical devices and sterile and non-sterile active medical devices (incl. monitoring and software) for continuous blood glucose monitoring systems.

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). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 120783 0001 Rev. 01

Report No.: TW2410501

Valid from: 2025-01-13
Valid until: 2026-12-10

Date, 2025-01-13

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

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

Design and Development, Manufacturing and Distribution of in-vitro diagnostic instruments and reagents (meters, test strips, control solutions) for clinical chemistry used to monitor physiological parameters in blood (incl. self-testing / point of care), and for immunochemistry (analyzers, cartridges. control solutions) used to monitor physiological parameters in blood and urine (incl. point of care).

Servicing of in-vitro diagnostic instruments for clinical chemistry and Immunochemistry used to monitor physiological parameters in blood or urine (incl. self-testing / point of care).

Distribution of in-vitro diagnostic reagents for infectious disease diagnosis (colloidal gold method).

The provision of Design and Development, Manufacturing, Warehousing and Distribution services for sterile non-active, non-implantable medical devices and sterile and non-sterile active medical devices (incl. monitoring and software) for continuous blood glucose monitoring systems.

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

Manufacture of electrode card as a component in test strips.

Design and Development, Manufacturing of in-vitro diagnostic reagents for infectious disease diagnosis (colloidal gold method).

The provision of Manufacturing, Warehousing and Distribution services for sterile non-active, non-implantable medical devices for continuous glucose monitoring systems.

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