

EC Certificate



**Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)**

Registration No.: HL 2100077-1

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

Products: Meters for self-testing

- Blood Glucose Meters
- Blood Uric Acid Meters
- Blood Glucose and Uric Acid Meters
- Blood Cholesterol Meters
- Blood Glucose and Cholesterol Meters
- Blood Hemoglobin Meters
- Blood Lactate Meters
- Blood Glucose and Ketone Meters
- Blood Ketone Meters
- Blood Glucose, Cholesterol, Triglyceride, and Uric Acid Meters

Test Strips for self-testing

- Blood Glucose Test Strips
- Blood Uric Acid Test Strips

The Notified Body hereby declares that the requirements of Annex IV, excluding sections 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 238515796-030
Effective date: 2022-03-31
Expiry date: 2025-05-26
Issue date: 2022-03-31



A handwritten signature in blue ink, likely belonging to Wenxiang Zhang.

Wenxiang Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

EC Certificate



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Annex IV excluding (4, 6)

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Manufacturer: Apex Biotechnology Corp.
No. 7, Li-Hsin Road V
Hsinchu Science Park
Hsinchu
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- Blood Cholesterol Test Strips
- Blood Hemoglobin Test Strips
- Blood Lactate Test Strips
- Blood Ketone Test Strips
- Blood Triglyceride Test Strips

Control Solutions for self-testing

- Glucose Control Solutions
- Uric Acid Control Solutions
- Cholesterol Control Solutions
- Hemoglobin Control Solutions
- Lactate Control Solutions
- Ketone Control Solutions
- Triglyceride Control Solutions

Replaces Approval, Registration No. HL 60146755 0001

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Hsinchu Science Park
Hsinchu
Taiwan

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	Apex Biotechnology Corp. No. 180, Ln.70, Wuqing Rd., Dayuan Dist., Taoyuan City 337 Taiwan	Electrode Card of Test Strips

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