

EC Certificate
Directive 98/79/EC Annex IV, excluding Sections 4 and 6
Full Quality Assurance System
In Vitro Diagnostic Medical Devices

Registration No.: HL 60146755 0001

Report No.: 50152566 005

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

Products: IVD Medical Devices
(see attachment for additional site and products included)
Replaces Approval, Registration No. HL 60133486 0001

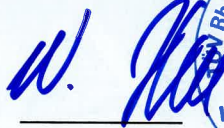
Expiry Date: 2023-09-12

The Notified Body hereby declares that the requirements of Annex IV, excluding section 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.

Effective Date: 2020-07-22

Date: 2020-07-22

Notified Body


Dipl.-Ing. W. Hsu



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HL 60146755 0001
Report No.: 50152566 005

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
- Blood Cholesterol Test Strips
- Blood Hemoglobin Test Strips
- Blood Lactate Test Strips
- Blood Ketone Test Strips
- Blood Triglyceride Test Strips

Date: 2020-07-22

Notified Body

W. Hsu
Dipl.-Ing. W. Hsu



**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Certificate**

Registration No.: HL 60146755 0001
Report No.: 50152566 005

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

Products:

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

Site included:

Apex Biotechnology Corp.
No. 180, Ln. 70, Wuqing Rd., Dayuan Dist.,
Taoyuan City 337, Taiwan

Date: 2020-07-22

Notified Body

W. Hsu
Dipl.-Ing. W. Hsu

