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 60121584 0001

Report No.: 15068064 005

Manufacturer:

Wuxi Biohermes Bio & Medical
Technology Co., Ltd.
No. 136 Mashan Meiliang Road, Binhu
Wuxi
214092 Jiangsu
China

Products:

- GluCoA1c Blood Glucose and Glycohemoglobin Analysis System for self-testing
- Glycohemoglobin Analysis System for self-testing

(see attachment for additional site included)

Expiry Date: 2022-04-23

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: 2017-12-27

Date: 2017-12-27

Notified Body

X. Ren

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.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HL 60121584 0001
Report No.: 15068064 005

Manufacturer:
Wuxi Biohermes Bio & Medical Technology Co., Ltd.
No. 136 Mashan Meiliang Road, Binhu
Wuxi
214092 Jiangsu
China

Site included:

11th Floor, 530 Mansion, #18 Qingyuan Road,
Xinwu District, Wuxi 214135, China

Notified Body

Date: 2017-12-27

X. Ren

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle III