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 60141764 0001

Report No.: 15073607 018

Manufacturer:

Andon Health Co., Ltd.
No. 3 Jinping Street,
YaAn Road, Nankai District
Tianjin, 300190
China

Products:

In Vitro Diagnostic Medical Devices

(see attachment for products and additional site included)

Replaces Approval, Registration No.: HL 60107769 0001

Expiry Date: 2024-05-27

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: 2019-08-08

Date: 2019-08-08

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Herbert Zhong

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 60141764 0001
Report No.: 15073607 018

Manufacturer:
Andon Health Co., Ltd.
No. 3 Jinping Street,
YaAn Road, Nankai District
Tianjin, 300190
China

Products:

Blood Glucose Meters, Blood Glucose Test Strips for Self-testing, Digital Pregnancy Tests, Digital Ovulation Tests, Digital Pregnancy and Digital Ovulation Tests, Pregnancy Test Strips, Ovulation Test Strips

Site included:

Andon Medical Co., Ltd.
No.26 HangYu Road, Tianjin Airport Economic Area,
Tianjin 300380, China

Date: 2019-08-08

Notified Body
TÜVRheinland LGA Products GmbH Zertifizierungsstelle
Herbert Zhong