

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 60095728 0001

Report No.: 15073607 001

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 sites included)

Replaces Approval, Registration No.: HL 60091117 0001

Expiry Date: 2019-11-05

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: 2014-11-19

Date: 2014-11-19



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 60095728 0001
Report No.: 15073607 001

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

Production site 1: Andon Health Co., Ltd.
No.3 Jinping Street, YaAn Road, Nankai District,
Tianjin, 300190, China

Manufacture of Blood Glucose Meters

Production site 2: Andon Medical Co., Ltd.
No.26 HangYu Road, Tianjin Airport Economic Area,
Tianjin 300380, China

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

Date: 2014-11-19

Notified Body



S. Liu