

APPROVAL
EC Directive 98/79/EC Annex IV, Article 3
Full Quality Assurance System
In vitro diagnostic medical devices

Registration No.: HL 60027602 0001

Report No.: 15033511 001

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

Tianjin, 300190
China

Scope: Design and Development, Manufacture of
In Vitro Diagnostic Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HL 60023653 0001

Date of Expiry: 03.12.2014

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex IV, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex IV, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notified Body

Date 22.01.2010


Dipl.-Ing. D. Meier

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. **0197** to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. **CE**

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: HL 60027602 0001
Report No.: 15033511 001

Manufacturer: Andon Health Co., Ltd.
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YaAn Road, Nankai District

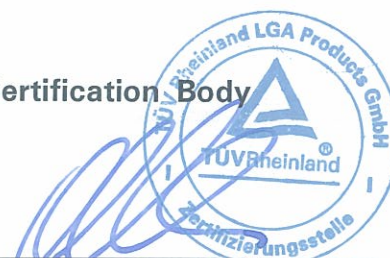
Tianjin, 300190
China

Scope: 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

Date 22.01.2010

Certification Body



Dipl.-Ing. D. Meier