EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60097963 0001

Report No.: 15073607 001

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

Products:
Medical Devices

(see attachment for products and additional site included)

Replaces Approval, Registration No.: HD 60095727 0001

Expiry Date: 2019-11-05

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2014-11-25

Date: 2014-11-25

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

S. Liu

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning 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.: HD 60097963 0001
Report No.: 15073607 001

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

Products:

Electronic Sphygmomanometers, Electrical Muscle Stimulators, TENs Devices, Foetal Dopplers, Handheld Massagers, Rhinitis Retrievers, Blood Viscosity Therapeutic Equipments, Phototherapy Devices, Hypertension Treatment Devices, Portable ECG Monitors, Pulse Oximeters

Production site included:

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

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierstelle TÜVRheinland

Date: 2014-11-25

S. Liu