



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

**Registration No.:** HD 60141761 0001

**Report No.:** 15073607 018

**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 60132189 0001

**Expiry Date:** 2024-05-27

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:** 2019-08-08

**Date:** 2019-08-08

Notified Body



**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.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HD 60141761 0001  
**Report No.:** 15073607 018

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

**Products:**

Ambulatory Blood Pressure Monitors, 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

**Date:** 2019-08-08

**Notified Body**  
  
**Herbert Zhong**