

**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



**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.

