Product Service

# CERTIFICATE

**No. Q5 17 08 71993 015**

**Holder of Certificate:** **Little Doctor Electronic ( Nantong ) Co., Ltd.**
No.8, Tongxing Road
Economic &Technical Development Area
226010 Nantong, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):** Little Doctor Electronic ( Nantong ) Co., Ltd.
No.8, Tongxing Road, Economic &Technical Development Area, 226010 Nantong, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

**Scope of Certificate:** **Design and Development, Production and Distribution of Aneroid sphygmomanometers, Blood pressure monitor, Nebulizer, Stethoscopes, Dental oral irrigator, Examination light Production and distribution of Digital thermometer**

**Applied Standard(s):** EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** SH1740414

**Valid from:** 2017-10-12
**Valid until:** 2020-09-30

040527686511181

**Date,** 2017-10-12

Stefan Preiß

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00







TÜV®

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TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS CRT2 / 10.13

Digitally signed by Potînga Stela
Date: 2019.02.13 15:55:37 EET
Reason: MoldSign Signature
Location: Moldova

乐道克电子制造（南通）有限公司
LITTLE DOCTOR ELECTRONIC (NANTONG) CO., LTD.

No. 8 Tongxing Road
Economic and Technical
Development Area
Nantong Jiangsu
P.R. of China
Tel.: +86 0513 85986718

# Declaration of Conformity

| | |
|---|---|
| Manufacturer:<br>Address: | **LITTLE DOCTOR ELECTRONIC (NANTONG) CO., LTD.**<br>No. 8 Tongxing Road, Economic and Technical Development Area, Nantong, Jiangsu, P.R. China |
| EU Representative: | **LITTLE DOCTOR EUROPE SP. Z O. O.**<br>**(st. Zawila 57G, 30-390 Krakow, Poland)** |
| Product:<br>Model Code: | Aneroid Sphygmomanometer and Accessories<br>**LD-71** |

Classification (MDD, Annex IX): **IIa**

We herewith declare that the above mentioned product meet the provisions of the following EC Council Directive and Standards. All supporting documentation are retained under the premise of manufacturer and the notify body.

| | **Directives** |
|---|---|
| General Applicable Directives: | The COUNCIL DIRECTIVE 93/42/EEC concerning Medical Devices (MDD 93/42/EEC) |
| Standards: | ISO13485:2003 and all applicable harmonized standards (published in the Official Journal of the European Communities). |
| Notified Body: | TÜV SUD Product Service GmbH<br>Zertifizierstelle Ridlerstrabe, 65 80339 Munchen, Germany |
| Certificate: | G2M 16 04 71993 013 |
| Expiration date of the Certificate: | 15.06.2021 |
| Data CE mark was affixed: | June 2011 |
| Place, Date: | Nantong, 23.06.2016 |

Signature: .....
Name: Pan Xinhua
Position: General Manager