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: Address:	**LITTLE DOCTOR ELECTRONIC (NANTONG) CO., LTD.** No. 8 Tongxing Road, Economic and Technical Development Area, Nantong, Jiangsu, P.R. China
EU Representative:	**LITTLE DOCTOR EUROPE SP. Z O.O.** St. Zawila 57G 30-390 Krakow POLAND
Product: Model Code:	Electronic Blood Pressure Monitors and Accessories **LD51S**

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:	DIRECTIVE 93/42/EEC on Medical Devices (MDD), Annex V (Devices in Class IIa, IIb or III)
Standards:	ISO 13485, EN980, EN1041, EN1060-1, EN1060-3, 60601-1-2, ISO 14971, European Directive 2002/95/EC(RoHS)
Notified Body:	TÜV SUD Product Service GmbH Zertifizierstelle Ridlerstrasse 65, 80339 Munchen, Germany
Certificate:	G2 16 05 71993 014
Expiration date of the Certificate:	2020.10.09
Data CE mark was affixed:	2010, October
Place, Date:	Nantong, 2016.07.22

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

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

Digitally signed by Potînga Stela
Date: 2019.04.11 13:51:59 EEST
Reason: MoldSign Signature
Location: Moldova

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

Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 15 08 71993 012

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

EC-Representative:
Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):
Blood Pressure Monitor,
Digital Thermometer
Ultrasonic Nebulizer,
Compressor Nebulizer

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH15404EXT01

Valid from: 2015-10-10
Valid until: 2020-10-09

Date, 2015-10-08

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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

Product Service

EC Certificate
Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 15 08 71993 012

Facility(ies):

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

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

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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

Date, 2017-10-12

Stefan Preiß

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

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