P.R. of China Tel.: +86 0513 85986718

Declaration of Conformity

Manufacturer:

LITTLE DOCTOR ELECTRONIC (NANTONG) CO., LTD.

Address:

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:

Examination Light (Visual Diagnostic Device)

LD-V09

Classification (MDD, Annex IX): I

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:

EN ISO 13485:2016

Medical devices – Quality management systems –

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

Certificate:

Q5 17 08 71993 015

Notified Body:

TÜV SUD Product Service GmbH

Zertifizierstelle Ridlerstrasse 65, 80339 Munchen,

Germany

Expiration date of the Certificate: 30.09.2020

Data CE mark was affixed:

October, 2014

Place, Date:

Nantong, 20.10.2017

Signature: ..

Name: Pan Xinhua

Position: General Manager