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

TÜV SÜD
Product Service

Certificate

No. Q5 101251 0001 Rev. 00

Holder of Certificate: **Shenzhen LEPU Intelligent Medical Equipment Co.,Ltd.**
North side of floor 3, BLD 9
BaiWangxin High-Tech Industrial Park
Songbai Road, Xili Street, Nanshan District
518055 Shenzhen, Guangdong Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Shenzhen LEPU Intelligent Medical Equipment Co.,Ltd.
North side of floor 3, BLD 9, BaiWangxin High-Tech Industrial Park, Songbai Road, Xili Street, Nanshan District, 518055 Shenzhen, Guangdong Province, 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 Fingertip pulse oximeter, Digital ultrasonic imaging scanner.**

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.: BJ1812101

Valid from: 2018-12-03
Valid until: 2021-12-02

Date, 2018-12-03

Stefan Preiß

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany