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ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 101251 0002 Rev. 00

Manufacturer:

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

EC-Representative:

Lepu Medical (Europe) Cooperatief U.A.
Abe Lenstra Boulevard 36, 8448 JB Heerenveen, THE NETHERLANDS

Product Category(ies): Fingertip pulse oximeter, Digital ultrasonic imaging scanner.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

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Valid until: 2023-12-02

Date, 2018-12-03

Stefan Preiß

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

A4 / 07.17

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Shenzhen LEPU Intelligent Medical Equipment Co.,Ltd.
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