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

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Date: 2022.07.29 12:06:24 EEST
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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 18 02 36868 047

Manufacturer:

Shanghai Lishen Scientific Equipment Co., Ltd.
No. 6788, Songze Avenue, Qingpu
201706 Shanghai
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):

High Frequency Surgical Units, Anaesthetic Machine, Easy ECG Monitor, Handheld Pulse Oximeter, Wrist Oximeter, Fingertip Oximeter, Fetal Doppler

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.

Report No.: SH18096EXT01

Valid from: 2018-05-21
Valid until: 2023-05-20

04052768706881

Date, 2018-03-19

Stefan Preiß

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

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Facility(ies):

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No. 6788, Songze Avenue, Qingpu, 201706
Shanghai, PEOPLE'S REPUBLIC OF CHINA

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

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