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

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 17 11 89075 004

Facility(ies):

Shanghai Sunbright Industrial Co., Ltd
No. 778 Siping Road, Hongkou District,
Shanghai, China

Digitally signed by Jighili Tatiana
Date: 2019.11.01 16:19:20 EET
Reason: MoldSign Signature
Location: Moldova

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

TÜV®

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No. G1 17 11 89075 004

Manufacturer:

Shanghai Sunbright Industrial Co., Ltd

No. 778 Siping Road,
Hongkou District,
Shanghai, China

EC-Representative:

KINGSMEAD SERVICE LIMITED

19 MEZZANINE FLOOR 19-21
CRAWFORD STREET
London
W1H 1PJ
UNITED KINGDOM

Product Category(ies):

Patient Monitor, Fetal Monitor, B-ultrasound Diagnostic System, Color Doppler Diagnostic System, Electrocardiograph, Syring Pump, Infusion Pump, 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.: SH1787804_RA

Valid from: 2019-03-06
Valid until: 2021-02-03

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Date, 2019-03-06

Stefan Preiß

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

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