



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

**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, Syringe 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

**Date,** 2019-03-06

Stefan Preiß



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

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