

MED/CERT

Certificate

The Certification Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith confirms that the company

Shanghai Sunbright Industrial Co., Ltd
No. 588 Mingcheng Road, Fengxian District,
Shanghai-China

has introduced and applies a Quality Management System in the area of

Specification as per attachment

A Quality Audit demonstrated compliance of the Quality Management System with

EN ISO 13485:2003 + AC:2007

The certification assumes that the company is applying and maintaining its
Quality Management System according to the above given standard.

The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 01 June 2021
Hamburg, 20 December 2014:

Process No.: QS - 6730
Certificate No.: 6730GB431101220


MEDCERT Certification Body
(Frank Wilmerstaedt)





Attachment
Certificate – QS - 6730

**Design, manufacture and distribution of
pulse oximeter, pocket fetal doppler, visual stethoscope,
patient monitor, fetal monitor, ECG, ECG acquisition box, holter,
B-ultrasound diagnostic system, ambulatory blood pressure monitor,
EEG, anaesthesia machine, ventilator, auto chemistry analyzer,
fully auto hematology analyzer, microplate reader,
microplate washer, electrosurgical unit, colposcope, dental units,
operation table, operation light, infusion pump, syringe pump**

The attachment is valid only in connection with
certificate-No: 6730GB431101220

Hamburg, 20 December 2014:


MEDCERT Certification Body
(Frank Wilmerstaedt)

The Notified Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith confirms that the company

**Shanghai Sunbright Industrial Co., Ltd
No. 588 Mingcheng Road, Fengxian District,
Shanghai-China**

has introduced and applies a Quality Management System
for the products / product category

**Pulse oximeter, pocket fetal doppler, visual stethoscope,
patient monitor, fetal monitor, B-ultrasound diagnostic system,
ECG, ECG acquisition box, ambulatory blood pressure monitor,
EEG, anaesthesia machine, ventilator, holter, electrosurgical unit,
infusion pump and syringe pump**

An Audit demonstrated compliance of the Quality Management System with

Annex II
excluding section (4)

of the **Council Directive 93/42/EEC concerning Medical Devices.**

The certification assumes that the company is applying and maintaining its Quality Management System according to the above given annex. The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 01 June 2021
Hamburg, 20 December 2014

Process No.: QS - 6730
Certificate No.: 6730GB410101220
MEDCERT Identification No.: 0482


MEDCERT Certification Body
Frank Wülmerstaedt



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-983.94.13