CERTIFICAT ◆ CERTIFICATE ◆ 認証書 ◆ 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 07 49076 014

Manufacturer:

Shenzhen Creative Industry Co., Ltd.
2/F, Block 3
Nanyou Tian'an Industry Town
518054 Shenzhen, GD
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

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

Product Category(ies):

Patient Monitor, Vital Signs Monitor, Fetal Doppler, Fingertip Oximeter, Handheld Pulse Oximeter, Wrist Oximeter, Easy ECG Monitor, Spot-Check Monitor, SpO2 Probe, Sleep Screener, Multi Parameter Monitors for Capnography and Pulse Oximetry

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.: GZ1715301

Valid from: 2018-01-15
Valid until: 2020-10-12

Date, 2018-01-15

Stefan Preiß

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

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Facility(ies):

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GD, PEOPLE'S REPUBLIC OF CHINA