Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

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 004372 0005 Rev. 00

Manufacturer:

Shenzhen Prunus Medical Co.,Ltd.
6th Floor and Zone A of 9th Floor
Block C, No. 71-3
Xintian Road, Fuyong Street
Bao'an District
518103 Shenzhen, Guangdong
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Shenzhen Prunus Medical Co.,Ltd.
6th Floor and Zone A of 9th Floor, Block C, No. 71-3, Xintian Road, Fuyong Street, Bao'an District, 518103 Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Anesthesia Machine, Ventilator, Air Compressor, Respiratory Humidifier, Vaporizer, Emergency and Transport Ventilator, Full Digital Ultrasonic Diagnostic Instrument, Patient Monitor

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.: GZ1915801

Valid from: 2019-12-18
Valid until: 2024-05-26

Date, 2019-12-18

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Turcanu Stefan
Date: 2019.12.25 10:32:07 EET
Reason: MoldSign Signature
Location: Moldova

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

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