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

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Declaration of Conformity

CE 0123

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

EC Representative: Wellkang Limited
The Black Church, St. Mary's Place, Dublin 7, D07 P4AX, Ireland

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

Model/PN: See attachment 1

Classification: See attachment 1

Conformity Assessment Route: MDD Annex II excluding(4)

We, Shenzhen Prunus Medical Co., Ltd., herewith declare that the stated medical devices meet the transposition into national law, the provisions of Council Directive 93/42/EEC concerning Medical Devices, as amended by 2007/47/EC. All supporting documentations are retained at the premises of the manufacturer.

Notified Body: TÜV SÜD Product service GmbH
Ridlerstraße 65
80339 München, Germany.

Identification Number : 0123

(EC) Certificate(s): G1 004372 0005 Rev. 00

The Certificate is valid until 2024-05-26

Place, Date of Issue: Shenzhen, 2019-12-21

Signature: Hu Yujie 2019.12.21

Name of Authorized signatory: Miss Hu Yujie

Position Held in Company: Regulatory Director

Attachment 1

NO.	Device Name	Model	Classification
1	Anesthesia Machine	Boaray 600, Boaray 700	IIb
2		Boaray 600C, Boaray 600D	IIb
3		Boaray 700C, Boaray 700D	IIb
4	Ventilator	Boaray 3000C , Boaray 3000D	IIb
5		Boaray 5000C , Boaray 5000D	IIb
6		Boaray 2000D, Boaray 2000C	IIb
7	Air Compressor	Boaray 10A	IIa
8	Respiratory Humidifier	Boaray 500D, Boaray 500C	IIa
9	Vaporizer	Boaray 60, Boaray 80	IIb
10	Emergency and Transport Ventilator	Boaray 1000A , Boaray 1000B , Boaray 1000C , Boaray 1000D	IIb
11	Full Digital Color Ultrasonic Diagnostic Instrument	AFS-4000, AFS-5000	IIa
12	Patient Monitor	XH-60A, XH-60D	IIb