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Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
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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. 01**

**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

**Product Category(ies): Anesthesia Machine, Ventilator, Air Compressor, Respiratory Humidifier, Vaporizer, Emergency and Transport Ventilator, 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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G10043720005Rev.01](http://www.tuvsud.com/ps-cert?q=cert:G10043720005Rev.01)

**Report No.:**

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**Valid from:**

2021-04-07

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2024-05-26

**Date,**

2021-04-07

Christoph Dicks

Head of Certification/Notified Body