



Product Service

CERTIFICATE

No. Q1N 12 12 73322 006

Holder of Certificate: **Beijing Anesthesia Medical Co.Ltd**
 No.31,Yongwang Road,Beijing Bioengineering and
 Medicine Industry Base,Huangcun Town,Daxing district,
 Beijing,10086
 PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Beijing Anesthesia Medical Co.Ltd
 No.31,Yongwang Road,Beijing Bioengineering and Medicine
 Industry Base,Huangcun Town,Daxing district,Beijing,10086
 REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design, Development, Production and Service of
 Disposable Introducer Kit, Disposable Central
 Venous Catheter Kit, PICC Catheter Kit, Introducer needle, Guidewire,
 Heparin cap, Guidewire introducer syringe, Dialysis Catheter Kit
 Foley Catheter**

Applied Standard(s): EN ISO 13485:2012/AC:2012
 ISO 13485:2012
 Medical Devices – Quality Management Systems –
 Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: BJ1372306
Valid from: 2017-04-26
Valid until: 2020-04-25




Date, 2016-12-11
 Hans-Heiner Junker

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TÜV SÜD Product Service GmbH
 Zertifizierstelle
 Ridlerstraße 65 · 80339 München
 Germany



Akkreditiert durch
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln
 und Medizinprodukten
 ZLG-ZQ-999.98.12-46

TÜV®



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 15 11 73322 009

Manufacturer: **Beijing Anesthesia Medical Co.,Ltd**
No.31, Yongwang Road, Beijing Bioengineering and
Medicine Industry Base, Huangcun Town, Daxing district,
Beijing, 10086
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: **Shanghai International Trading
Corp .GmbH (Hamburg)**
Eiffestrasse 80
20537 Hamburg
GERMANY

**Product
Category(ies):** **Disposable Introducer Kit, Disposable Central
Venous Catheter Kit, PICC Catheter Kit, Introducer needle, Guidewire,
Heparin cap, Guidewire introducer syringe, Dialysis Catheter Kit**

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.: BJ1571105-1
Valid from: 2015-08-25
Valid until: 2020-08-24



Date, 2015-07-24
Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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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 15 11 73322 009

Facility(ies):

Beijing Anesthesia Medical Co.Ltd
No.31,Yongwang Road,Beijing Bioengineering and Medicine
Industry Base,Huangcun Town,Daxing district,Beijing,10086
REPUBLIC OF CHINA