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 064271 0019 Rev. 01

Manufacturer: **Tianjin Medis Medical Device Co., Ltd.**
No.15-A, Saida One Avenue
Xiqing Economic Development Area
300385 Tianjin
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: **Shanghai International Holding Corp. GmbH (Europe)**
Eiffestraße 80, 20537 Hamburg, GERMANY

Product Category(ies): **Laryngeal Mask, Silicone Foley Catheters, Endotracheal Tubes, Nasopharyngeal Airway, Bougie, Tracheostomy tube, Pressure indicator.**

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.: BJ18947031

Valid from: 2019-02-13
Valid until: 2022-12-20

Date, 2019-02-13

Stefan Preiß

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

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

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

TÜV SÜD 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 064271 0019 Rev. 01

Facility(ies):

Tianjin Medis Medical Device Co., Ltd.
No.15-A, Saida One Avenue, Xiqing Economic Development Area,
300385 Tianjin, PEOPLE'S REPUBLIC OF CHINA

Tianjin Medis Medical Device Co., Ltd.
South Street, Liuhe Town, Qing County, 062650 Cangzhou City,
Hebei Province, PEOPLE'S REPUBLIC OF CHINA

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

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

TÜV®