

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)

G1 14 10 64271 011 No.

Manufacturer: Tianjin Medis Medical Device Co., Ltd.

> 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road

Xiqing Economic Development Area

300385 Tianjin City

PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Shanghai International Holding

Corp. GmbH (Europe)

Eiffestraße 80 20537 Hamburg **GERMANY**

Product

Laryngeal Mask and Oxygen Mask, T-bag, Silicone Foley Catheters, Category(ies):

> **Endotracheal Tubes**, Nasopharyngeal Airway.

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.: BJ1494704-1

Valid from: 2015-01-07 Valid until:

2017-12-20





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

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Date,

2015-01-08

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Facility(ies):

Tianjin Medis Medical Device Co., Ltd.

10-A Tianzhi Industrial Center, No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City, PEOPLE'S

REPUBLIC OF CHINA

Tianjin Medis Medical Device Co., Ltd.

No. 37 Min He Road, Xiqing Economic Development Area,

300385 Tianjin, PEOPLE'S REPUBLIC OF CHINA