



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

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 001281 0001 Rev. 02

仅限存档使用

Manufacturer:

**Guangzhou AMK
Medical Equipment Co., Ltd.**

No. B13 and B14
Huachuang Industry Park
Jinshan Cun
Shiqi Town
Panyu District
511450 Guangzhou
PEOPLE'S REPUBLIC OF CHINA

Product
Category(ies):

**Sterile Non-active Medical Devices
(See the attachment for detailed
information)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.:

SH20122201

Valid from:

2020-04-29

Valid until:

2024-05-26

Date,

2020-04-29

Christoph Dicks
Head of Certification/Notified Body



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For the product(s)/product category (ies):

Disposable Endotracheal Tubes,

Laryngeal Mask Airways,

Disposable Endobronchial Tubes,

Disposable Closed Suction Catheters,

Disposable Intubating Stylets,

PVC Hydrophilic Urethral Catheters,

Nasopharyngeal Airways,

Gabriel Feeding Tubes with Balloon for single use,

Disposable Endobronchial Blocker Tubes,

Ureteral Dilation Balloon Catheters,

Urodynamic Catheters,

Rectal Pressure Catheters,

Ureteral Access Sheaths,

Ureteral Stent Sets,

Disposable Cervical Ripending Balloon Catheters