



Certificate

No. Q5 001281 0002 Rev. 02

仅限存档使用

Holder of Certificate: **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

Certification Mark:



Scope of Certificate: **Design and Development,
Production and Distribution of
Sterile Non-active Medical Devices
(See the attachment for detailed
information)**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 001281 0002 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_001281_0002_Rev.02)

Report No.: SH20122202

Valid from: 2020-12-01

Valid until: 2023-11-30

Date, 2020-12-01

Christoph Dicks
Head of Certification/Notified Body

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Certificate

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Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): 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

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

**Design and Development, Production and Distribution of
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,
Medical Face Masks, Surgical Masks, Medical Protective Masks**

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