A4 / 07.17



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

Product Service

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: Valid until: 2020-04-29 2024-05-26

Date, 2020-04-29

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Christoph Dicks Head of Certification/Notified Body





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

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

Page 2 of 2 TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123







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

Report No.:

SH20122202

Valid from: Valid until: 2020-12-01 2023-11-30

Christoph Dicks Head of Certification/Notified Body

Date,

2020-12-01





Certificate

仅限存档使用

No. Q5 001281 0002 Rev. 02

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