Product Service

CERTIFICATE

No. Q6 17 09 77823 003

Holder of Certificate: **Jiangsu Kaishou Medical Apparatus Co., Ltd.**
Sanhekou Street, Zhenglu Town
213115 Changzhou City
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Jiangsu Kaishou Medical Apparatus Co., Ltd.
Sanhekou Street, Zhenglu Town, 213115
Changzhou City, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

Scope of Certificate: **Production and Distribution of Vaginal Speculum, Silicone Suction Reservoir and Flat Drain (Round Drain), Endotracheal Tube, Reinforced Endotracheal Tube, Tracheostomy Tube, Silicone Foley Catheter, Disposable Colostomy Collection Bag**

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

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1771007

Valid from: 2018-01-23
Valid until: 2021-01-09

Date, 2018-01-23

Stefan Preiß

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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Date, 2018-01-23

Stefan Preiß

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 17 09 77823 011

Manufacturer:

Jiangsu Kaishou Medical Apparatus Co., Ltd.
Sanhekou Street, Zhenglu Town
213115 Changzhou City
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Wellkang Ltd
Suite B, 29 Harley Street
LONDON
W1G 9QR
UNITED KINGDOM

Product Category(ies):

Vaginal Speculum

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: SH1771007

Valid from: 2018-01-23
Valid until: 2022-01-09

Date, 2018-01-23

Stefan Preiß

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

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate
Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 17 09 77823 011

Facility(ies):

Jiangsu Kaishou Medical Apparatus Co., Ltd.
Sanhekou Street, Zhenglu Town, 213115
Changzhou City, PEOPLE'S REPUBLIC OF CHINA

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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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 17 09 77823 010

Manufacturer:

Jiangsu Kaishou Medical Apparatus Co., Ltd.
Sanhekou Street, Zhenglu Town
213115 Changzhou City
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Wellkang Ltd
Suite B, 29 Harley Street
LONDON
W1G 9QR
UNITED KINGDOM

Product Category(ies):

Silicone Suction Reservoir and Flat Drain (Round Drain), Endotracheal Tube, Reinforced Endotracheal Tube, Tracheostomy Tube, Silicone Foley Catheter

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.: SH1771007

Valid from: 2018-01-23
Valid until: 2022-01-09

Date, 2018-01-23

Stefan Preiß

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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 17 09 77823 010

Facility(ies):

Jiangsu Kaishou Medical Apparatus Co., Ltd.
Sanhekou Street, Zhenglu Town, 213115
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