ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Production Quality Assurance System

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

No. G2 17 05 43199 023

Manufacturer:

Suzhou Hengxiang Import & Export Co., Ltd.
18F., 1638 Xi Huan Road
215004 Suzhou
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):

**Laparotomy Sponges,
X-Ray Detectable Gauze Swabs,
Surgical Gloves, Acupuncture Needles,
Surgical Blades, Disposable Syringes,
Infusion Sets, Blood Transfusion Sets,
Scalp Vein Sets,Sterile Hypodermic
Needle for Single Use, Syringe for Insulin,
Auto-disable Syringe, Nasal Oxygen Cannula,
Oxygen Mask, Endotracheal Tube,
Wound Drainage Reservoir,
Latex Foley Catheter, Humidifier Bottle,
Series of Nebulizer with Mask,
Extracorporeal Circulation Conduct of Blood
Purification Apparatus, First Aid Kits,
Digital Thermometers, Blood Pressure Monitors,
Infrared Ear Thermometers,
Infrared Forehead Thermometers**

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.: SH17116EXT01
Valid from: 2017-06-14
Valid until: 2022-06-13

Date, 2017-06-13

Stefan Preiß

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

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

No. G2 17 05 43199 023

Facility(ies):

Suzhou Hengxiang Import & Export Co., Ltd.
18F., 1638 Xi Huan Road, 215004 Suzhou,
PEOPLE'S REPUBLIC OF CHINA

Suzhou Hengxiang Import & Export Co., Ltd.
11F., 888 Chenghu Road, 215168 Suzhou,
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 I in sterile conditions, sterilised systems or procedure packs)

No. G2S 17 05 43199 024

Manufacturer:

Suzhou Hengxiang Import & Export Co., Ltd.
18F., 1638 Xi Huan Road
215004 Suzhou
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):

Sterile Urine Bag, Sterile Gauze Swabs,
Sterile Examination Gloves,
Vaginal Speculums,
Umbilical Cord Clamp,
Disposable I.D. Bracelets,
Wound Plaster, Wound Dressing

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.: SH17116EXT01

Valid from: 2017-06-14
Valid until: 2022-06-13



Date, 2017-06-13

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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 I in sterile conditions, sterilised systems or procedure packs)

No. G2S 17 05 43199 024

Facility(ies):

Suzhou Hengxiang Import & Export Co., Ltd.
18F., 1638 Xi Huan Road, 215004 Suzhou,
PEOPLE'S REPUBLIC OF CHINA

Suzhou Hengxiang Import & Export Co., Ltd.
11F., 888 Chenghu Road, 215168 Suzhou,
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Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex V
(Devices in class I with measuring function)

No. G2M 17 05 43199 025

Manufacturer:

Suzhou Hengxiang Import & Export Co., Ltd.
18F., 1638 Xi Huan Road
215004 Suzhou
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):

Aneroid Sphygmomanometer

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for the manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with the metrological requirements 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.: SH17116EXT01

Valid from: 2017-06-14
Valid until: 2022-06-13



Date, 2017-06-13

Stefan Preiß

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Directive 93/42/EEC on Medical Devices, Annex V
(Devices in class I with measuring function)

No. G2M 17 05 43199 025

Facility(ies):

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