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 16 07 78455 013

Manufacturer:

Zhanjiang Star Enterprise Co., Ltd.
No. 1, West Jinhua Road
Mazhang District
524094 Zhanjiang
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

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

Product Category(ies):

Foley Catheter (latex), Nelaton Catheter (latex), Endotracheal Tubes, Anesthesia Kits, Suction Catheter for Single Use in the Respiratory Tract, Disposable Urethral Catheterization Set, Urethral Catheters (PVC), Stomach Tube (PVC), Reinforced Endotracheal Tube

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.: SH16090EXT01

Valid from: 2016-09-17
Valid until: 2021-09-16

04052768093615

Date, 2016-08-23

Stefan Preiß

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

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 16 07 78455 013

Facility(ies):

Zhanjiang Star Enterprise Co., Ltd.
No. 1, West Jinhua Road, Mazhang District, 524094
Zhanjiang, PEOPLE'S REPUBLIC OF CHINA

Zhanjiang Star Enterprise Co., Ltd.
No. 49 Jinchuan Road, 524094 Zhanjiang,
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 15 06 78455 011

Manufacturer:
Zhanjiang Star Enterprise Co., Ltd.
No. 1, West Jinhua Road
Mazhang District
524094 Zhanjiang
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:
Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):
Male External Catheter
Male External Catheter(Silicone) /Silicone Condom Catheter,
Endotracheal Tube Holder,
Mouth Gag (mouth opener),
Drainage Bag

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.: SH15090EXT01

Valid from: 2015-09-16
Valid until: 2020-09-15

673188

Date, 2015-07-14

Hans-Heiner Junker

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

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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 15 06 78455 011

Facility(ies):

Zhanjiang Star Enterprise Co., Ltd.
No. 1, West Jinhua Road, Mazhang District, 524094
Zhanjiang, PEOPLE'S REPUBLIC OF CHINA

Zhanjiang Star Enterprise Co., Ltd.
No. 49 Jinchuan Road, 524094 Zhanjiang,
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TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 14 06 78455 010

Manufacturer:
Zhanjiang Star Enterprise Co., Ltd.
No. 1, West Jinhua Road
Mazhang District
524094 Zhanjiang
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:
Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):
Urethral Catheters (silicone), Tracheostomy Tubes for Single Use

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: SH1409014

Valid from: 2014-09-16
Valid until: 2019-09-15

Date, 2014-09-17

Hans-Heiner Junker

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Product Service

EC Certificate
Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 14 06 78455 010

Facility(ies):

Zhanjiang Star Enterprise Co., Ltd.
No. 1, West Jinhua Road, Mazhang District, 524094
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