Page 1 of 3

TÜV SÜD Product Service GmbH - Zertifizierstelle - Ridlerstraße 55 - 80339 München - Germany

Date, 2018-05-14

Stefan Preiß

Product Service

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Holder of Certificate: Products I/E Co., Ltd. **Zhejiang Medicines & Health**

PEOPLE'S REPUBLIC OF CHINA 310003 Hangzhou, Zhejiang ZMC Bldg,101-2,N.Zhongshan Rd

Zhejiang Medicines & Health Products I/E Co. Ltd. CHINA Hangzhou, Zhejiang, PEOPLE'S REPUBLIC OF ZMC Bidg,101-2,N.Zhongshan Rd., 310003

Facility(ies):

CERTIFI

Sterile hypodermic Syringes for single Use,









Sterile Burette Type Infusion Sets for Single Use

Cold and Hot Pack, Blood Transfusion Sets,

Certification Mark:

Scope of Certificate: **Production and Distribution of Medical Devices** (for detailed information see attachment)

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

Standard(s): Applied

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. The Certification Body of TUV SUD Product Service GmbH certifies that the company mentioned

2021-05-31 2018-06-01 04052768581150

Valid until: Valid from: Report No.:

SH1807620

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СЕРТИФИКАТ

Suction Connecting Tube with and without Yankauer, Disposable Surgical Blades Urinary Catheterization / Collection Kits, Oxygen Mask, Hemodialysis kit sterile, Tracheal Tubes,

Urine Bag, Tracheotomy Care Kits,

All Silicone Foley Catheters, **Urethral Catheters and Tracheal Tubes**

Urine Meters (W/Wo Urine Sampling Blunt Cannular), Dressing Kits,

Wound Dressing, Nasal Oxygen Cannula, Dental Needles for Single Use, Intubating Stylet, Tracheostomy Tubes

Medical Tape, Surgical Drapes, Surgical Gowns,

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STONTRACTE STANDA 18

Zinc Oxide Adhesive Plaster,

Surgical Elastic Bandages and Viscose Plaster Bandages Sterile Latex Surgical Gloves,

Sterile Latex Examination Gloves Colostomy Bag, Infusion Sets with PVC DEHP free for single Use.

Heparin Cap for single Use,

Page 2 of 3

Production and Distribution of

CADO

Disposable Arterial Venous Fistula Sets, Surgical Dressings and its related Products

Dialysis Blood Lines, Scalp Vein Sets,

Disposable Needles,

Supplement 001 dated 2018-05-14

Attachment for Certificate No Q6 18 03 38499 038

CERTIFICAT

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

Product Ser

TÜV SÜD Product Service GmbH - Zertifizierstelle - Ridicrstraße 65 - 80339 München - Germany

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Printer (117497-00 Printers (1774-177)

Page 3 of 3

Certification Medical Technology

Stefan Preiß

Munich, MHS-CRT, 2018-05-14

CARTO

Valid until:

Valid from:

2015-08-14 2020-08-13

Report No.:

SH15076EXT01

Supplement 001 dated 2018-05-14 Attachment for Certificate No Q6 18 03 38499 038

Suction Catheter, Sterile Vaginal Speculum for Single Use, Sterile I.V. Catheters for single Use, Feeding Set, Safety Syringes, Auto-disable Syringes

Nelaton Catheter, Feeding Tube,

Coveralls, Surgical Sheets, Face Masks,

Rectal Tube, Stomach Tube,

Surgical Caps, Shoe Covers,

Sterile and Non Sterile Nebulizer Mask, Wound Drainage Reservoir,

Orthopaedic Casting Bandage, Medical Bandage, Sterile and Non Sterile Anesthetic Mask,

Laryngeal Mask Airway, **PVC Examination Gloves**, Orthopaedic Padding,

Disposable Heat and Moisture Exchanger Filters Disposable Anesthetic Breathing Circuits,

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

CERTIFICAT

CERTIFICATE .

Manufacturer:

Products I/E Co., Ltd.

Zhejiang Medicines & Health

CERTIFICADO ◆

Z 0

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

認証証書

СЕРТИФИКАТ ◆

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ertificate

ZERTIFIKAT .

Date,

2015-07-02

GERMANY

22041 Hamburg Rantzaustr. 102 EC-Representative:

ZMC Hamburg GmbH

PEOPLE'S REPUBLIC OF CHINA 310003 Hangzhou, Zhejang ZMC Bldg, 105-2, N Zhongshan Rd

Product Category(ies):

attachment For detailed information please see

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 mandatory. See also notes overleaf surveillance. For marketing of class lib and ill devices an additional Annex III certificate is assurance system conforms to the requirements of this Directive and is subject to periodica The Certification Body of TUV SUD Product Service GmbH declares that the aforementioned

Page 1 of 3 TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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



Page 2 of 3

EC Certificate

Production Quality Assurance System (Devices in Class IIa, Ilb or III) Directive 93/42/EEC on Medical Devices (MDD), Annex V G2 15 05 38499 033

Facility(ies):

Hangzhou, Zhejiang, PEOPLE'S REPUBLIC OF Zhejiang Medicines & Health Products I/E Co., Ltd. ZMC Bldg,101-2,N.Zhongshan Rd., 310003



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TUV SUD Product Service 6mbH + Zertifízierstelle + Ridlerstraßa 65 + 80339 München + Garmany

CERTIFICAT

Supplement 001 dated 2015-07-02

Attachment for Certificate No G2 15 05 38499 033

СЕРТИФИКАТ ◆ CERTIFICADO 認証証書 C

Tracheostomy Tubes,

ZERTIFIKAT •

CERTIFICATE .

Munich, 2015-07-02

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Scalp Vein Sets, Dialysis Blood Lines,

Disposable Needles,

Disposable Arterial Venous Fistula Sets,

Sterile Latex Surgical Gloves

Gauze Balls and Lap Sponges in Sterilization Packaging.

X-Ray Detectable Gauze Swabs (Sponges)

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

Nasal Oxygen Cannula

Sterile Hypodermic Syringes for Single Use, Blood Transfusion Sets,

Disposable Infusion Sets,

Sterile Burette Type Infusion Sets for Single Use.

Tracheal Tubes, Oxygen Masks,

Urethral Catheters, Silicone Foley Catheters, Disposable Surgical Blades, Urinary Catheterization/Collection Kits, Hemodialysis Kit Sterile,

Safety Syringes, Sterile I.V. Catheters for single Use, Suction Connecting Tube with and without Yankauer, Infusion Sets with PVC DEHP free for single Use, Dental Needles for Single Use, Intubating Stylet, Auto-disable Syringes, Heparin Cap for Single Use,

Wound Drainage Reservoir Sterile and Non Sterile Anaethetic Mask Sterile and Non Sterile Nebulizer Mask Suction Catheter, Feeding Tube, Nelaton Catheter, Stomach Tube

Hans-Heiner Junker

Page 3 of 3

Product Service

TUV SUD Product Service GmbH = Zertifizierstelle + Ridlerstraße 65 + 80339 München + Germany

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(Devices in class I in sterile conditions, sterilised systems or procedure packs) **Production Quality Assurance System** Directive 93/42/EEC on Medical Devices (MDD), Annex V G2S 15 05 38499 034

Manufacturer:

EC-Representative:

ZMC Hamburg GmbH Rantzaustr. 102

22041 Hamburg

310003 Hangzhou, Zhejiang ZMC Bldg, 101-2, N. Zhongshan Rd. Products I/E Co., Ltd. Zhejiang Medicines & Health

PEOPLE'S REPUBLIC OF CHINA

Category(ies): Product

Coveralls, Surgical Caps, Shoe Covers, Rectal Tube, Surgical Sheets, Face Masks, Speculum for Single Use, Gloves, Feeding Set, Pre-filled Syringe, Blunt Cannular), Dressing Kits, Mucus Non-woven Wound Care products, Gauze Swabs (Sponges), Gauze Balls, Wound Dressings, Sterile Vaginal Medical Tape, Sterile Latex Examination Urine Bag, Gauze Bandages, Trap, Surgical Gowns, Surgical Drapes, Urine Meters (W/Wo Urine Sampling

Tracheotomy Care Kits

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

HEPUNIA

CERTIFICATE ◆

Valid from: Report No .:

Valid until:

2020-08-13 2015-08-14 SH15076EXT01

Hans-Heiner Junker

TUV SUD Product Service GmbH is Notified Body with identification no. 0123

Date,

2015-07-02

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Page 2 of 2

ZERTIFIKAT

TUY SUD Product Service GmbH • Zertifizierstelle • Ridlerstraße 55 = 90339 München • Germany

Product Service

Production Quality Assurance System EC Certificate (Devices in class I in sterile conditions, sterilised systems or procedure packs) Directive 93/42/EEC on Medical Devices (MDD), Annex V G2S 15 05 38499 034

Facility(ies):

CHINA Hangzhou, Zhejiang, PEOPLE'S REPUBLIC OF Zhejiang Medicines & Health Products I/E Co., Ltd. ZMC Bldg, 101-2,N. Zhongshan Rd., 310003

