

CERTIFICATE

No. Q6 18 03 38499 038



Product Service

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

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

Facility(ies):

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



Certification Mark:



Scope of Certificate:

Production and Distribution of Medical Devices (for detailed information see attachment)

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.:

SH1807820

Valid from:

2018-06-01

Valid until:

2021-05-31

Date: 2018-05-14

Stefan Pfeil

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DAKKS
Deutsche
Akkreditierungsstelle
D-53117 BONN

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



Product Service

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

Production and Distribution of
Surgical Dressings and its related Products,
Disposable Arterial Venous Fistula Sets,
Scalp Vein Sets,
Dialysis Blood Lines,
Disposable Needles,
Sterile hypodermic Syringes for single Use,
Blood Transfusion Sets,
Cold and Hot Pack,
Sterile Burette Type Infusion Sets for Single Use,
Tracheal Tubes,
Oxygen Mask,
Hemodialysis kit sterile,
Disposable Surgical Blades,
Suction Connecting Tube with and without Yankauer,
Urinary Catheterization / Collection Kits,
Tracheotomy Care Kits,
Urethral Catheters and Tracheal Tubes,
All Silicone Foley Catheters,
Urine Bag,
Urine Meters (W/Wo Urine Sampling Blunt Cannular),
Dressing Kits,
Tracheostomy Tubes,
Intubating Stylet,
Dental Needles for Single Use,
Nasal Oxygen Cannula,
Wound Dressing,
Surgical Gowns,
Surgical Drapes,
Medical Tape,
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,

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DAKKS
Deutsche
Akkreditierungsstelle
D-53117 BONN

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

Product Service



Auto-disable Syringes,
 Safety Syringes,
 Sterile I.V. Catheters for single Use, Feeding Set,
 Sterile Vaginal Speculum for Single Use,
 Suction Catheter,
 Feeding Tube,
 Melaton Catheter,
 Stomach Tube,
 Rectal Tube,
 Surgical Sheets,
 Face Masks,
 Coveralls,
 Surgical Caps,
 Shoe Covers,
 Wound Drainage Reservoir,
 Sterile and Non Sterile Nebulizer Mask,
 Sterile and Non Sterile Anesthetic Mask,
 Medical Bandage,
 Orthopaedic Casting Bandage,
 Orthopaedic Padding,
 PVC Examination Gloves,
 Laryngeal Mask Airway,
 Disposable Anesthetic Breathing Circuits,
 Disposable Heat and Moisture Exchanger Filters

Munich, MHS-CRT, 2018-05-14

S. P. Schmid

Stefan Pfeil
 Certification Medical Technology

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DAK5
 Medizinprodukte
 DIN EN ISO 13485

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 15 05 38499 033

Manufacturer: **Zhejiang Medicines & Health Products I/E Co., Ltd.**

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

EC-Representative: **ZMC Hamburg GmbH**

Rahnerstr. 102
 22041 Hamburg
 GERMANY

Product Category(ies): **For detailed information please see attachment**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacturing and final inspection of the respiratory 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.: SH15076EXT01

Valid from: 2015-08-14
 Valid until: 2020-08-13



Date, 2015-07-02

H. Heuer Junke
 Hans-Heuer Junke

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 (MD), Annex V
 (Devices in Class IIa, IIb or III)
No. G2 15 05 38499 033

Facility(ies):

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



Product Service

Attachment for Certificate No G2 15 05 38499 033
 Supplement 001 dated 2015-07-02

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

- X-Ray Detectable Gauze Swabs (Sponges),
- Gauze Balls and Lap Sponges in Sterilization Packaging,
- Sterile Latex Surgical Gloves,
- Disposable Arterial Venous Fistula Sets,
- Scalp Vein Sets, Dialysis Blood Lines,
- Disposable Needles,
- 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,
- Hemodialysis Kit Sterile,
- Disposable Surgical Blades,
- Urinary Catheterization/Collection Kits,
- Urethral Catheters, Silicone Foley Catheters,
- Tracheostomy Tubes,
- Intubating Stylet,
- Dental Needles for Single Use,
- Suction Connecting Tube with and without Yankauer,
- Infusion Sets with PVC DEHP free for single Use,
- Heparin Cap for Single Use,
- Auto-disable Syringes,
- Safety Syringes, Sterile I.V. Catheters for single Use,
- Suction Catheter, Feeding Tube,
- Nelaton Catheter, Stomach Tube,
- Sterile and Non Sterile Nebulizer Mask,
- Sterile and Non Sterile Anaesthetic Mask,
- Wound Drainage Reservoir

Munich, 2015-07-02

Hans-Heiner Junker



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 05 38499 034

Manufacturer:

Zhejiang Medicines & Health Products I/E Co., Ltd.

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

EC-Representative:

ZMC Hamburg GmbH

Ranzaustr. 102
22041 Hamburg
GERMANY

Product Category(ies):

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

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.:

SH15076EXT01

Valid From:

2015-08-14

Valid until:

2020-08-13

Date, 2015-07-02

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 05 38499 034

Facility(ies):

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

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