



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. Zhongshan Rd.
310003 Hangzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

ZMC Hamburg GmbH

Rantzastr. 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 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.:

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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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, PEOPLE'S REPUBLIC OF
CHINA



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