



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 03 38499 036

**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.:** SH1607618

**Valid from:** 2016-04-27  
**Valid until:** 2020-08-13



**Date,** 2016-04-26

*S. Preis*  
Stefan Preis

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

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(Devices in Class IIa, IIb or III)**No. G2 16 03 38499 036****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**



Attachment for Certificate No G2 16 03 38499 036

Supplement 001 dated 2016-04-27

Product Service

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 Anesthetic Mask,  
Wound Drainage Reservoir  
Laryngeal Mask Airway, Feeding Set,  
Disposable Anesthetic Breathing Circuits,  
Disposable Heat and Moisture Exchanger Filters,

Munich, CRT2, 2016-04-27

Stefan Preiß  
Certification Medical Technology

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