



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

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):

Gauze Swabs (Sponges), Gauze Balls, Urine Bag, Gauze Bandages, Non-woven Wound Care products, Urine Meters (W/Wo 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

Hans-Heiner Junker



Date, 2015-07-02

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

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Facility(ies):

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Hangzhou, Zhejiang, PEOPLE'S REPUBLIC OF
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