



Product Service

# EC - CERTIFICATE

## Production Quality Assurance System

(Annex V of the Directive 93/42/EEC on Medical Devices)

No. G2S 08 01 64937 002

<b>Manufacturer:</b>	<b>Suzhou Sunmed Co., Ltd.</b> No. 88 Shishan Road 215011 Suzhou PEOPLE'S REPUBLIC OF CHINA
<b>EC-Representative:</b>	<b>Shanghai International Holding Corp. GmbH (Europe)</b> Eiffestraße 80 20537 Hamburg GERMANY
<b>Product Category(ies):</b>	<b>Sterile Eye Pad, Sterile First-aid Dressing Bandage, Sterile Wound Plaster (Sterile Plaster Strips, Sterile Adhesive Wound Dressing), Sterile Non-adherent Dressing, Sterile Gauze Swab, Disposable Sterile Gown, Basic Dressing Pack, First Aid Kits, Sterile Non-woven Swabs, Sterile Lap Sponges without X-ray, Suction Catheters, Feeding Tubes, Stomach Tubes, Face Masks with Air Cushion</b>

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture according to Annex V, section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective product / product categories and conforms to the provisions of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: 70198732701

Valid until: 2013-02-18

Date, 2008-02-19

Reiner Krumme



TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

Page 1 of 2



Product Service

**EC-Certificate**

**Production Quality Assurance System**

(Annex V of the Directive 93/42/EEC on Medical Devices)

**No. G2S 08 01 64937 002**

**Facility(ies):**

**Suzhou Sunmed Co., Ltd.**

**No. 88 Shishan Road, 215011 Suzhou, PEOPLE'S  
REPUBLIC OF CHINA**



Product Service

# EC-CERTIFICATE

## Production Quality Assurance System

(Annex V of the Directive 93/42/EEC on Medical Devices)

No. G2 08 01 64937 003

**Manufacturer:**

**Suzhou Sunmed Co., Ltd.**

No. 88 Shishan Road  
215011 Suzhou  
PEOPLE'S REPUBLIC OF CHINA

**EC-Representative:**

**Shanghai International Holding Corp. GmbH (Europe)**

Eiffestraße 80  
20537 Hamburg  
GERMANY

**Product Category(ies):**

**Sterile Lap Sponges with X-ray,  
Sterile Gauze Swabs with X-ray,  
Sterile Surgical Blade, Blood Lancets,  
Scalp Vein Set for Single Use,  
Sterile Syringes for Single Use,  
Hypodermic Needles for Single Use,  
I.V. Cannula for Single Use,  
Sterile Heparin Caps for Single Use,  
Sterile Infusion Sets for Single Use,  
Digital Thermometers, Infra-red Ear Thermometers,  
Digital Blood Pressure Monitors  
(Digital Sphygmomanometer), Nelaton Catheters,  
Foley Catheter(Latex), Oxygen Masks,  
Nasal Oxygen Cannulae, Yankauer Suction  
Handles,  
Extension Tubes, CPR Masks, Nebulizers,  
Tracheal Tubes, Tracheotomy Tubes, Stopcocks**

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 products / product categories according to Annex V, section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class IIb and III products an additional Annex III - certificate is mandatory. See also notes overleaf.

**Report No.:**

70198732701

**Valid until:**

2013-02-18

**Date,** 2008-02-18

Reiner Krumme



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**EC-Certificate**  
**Production Quality Assurance System**  
(Annex V of the Directive 93/42/EEC on Medical Devices)  
**No. G2 08 01 64937 003**

**Facility(ies):** Suzhou Sunmed Co., Ltd.  
No. 88 Shishan Road, 215011 Suzhou, PEOPLE'S  
REPUBLIC OF CHINA



Product Service

# EC-CERTIFICATE

Production Quality Assurance System  
(Annex V of the Directive 93/42/EEC on Medical Devices)

No. G2M 08 01 64937 004

**Manufacturer:** Suzhou Sunmed Co., Ltd.  
No. 88 Shishan Road  
215011 Suzhou  
PEOPLE'S REPUBLIC OF CHINA

**EC-Representative:** Shanghai International Holding Corp. GmbH (Europe)  
Eiffestraße 80  
20537 Hamburg  
GERMANY

**Product Category(ies):** Thermometers for Medical Use, Sphygmomanometers

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for the manufacture according to Annex V, section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system covers those aspects of manufacture concerned with the metrological requirements of the respective product / product categories and conforms to the provisions of this Directive. It is subject to periodical surveillance. See also notes overleaf.

**Report No.:** 70198732701

**Valid until:** 2013-02-18

**Date,** 2008-02-18

Reiner Krumme



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Page 1 of 2



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**No. G2M 08 01 64937 004**

**Facility(ies):**

**Suzhou Sunmed Co., Ltd.**

**No. 88 Shishan Road, 215011 Suzhou, PEOPLE'S  
REPUBLIC OF CHINA**