



Product Service

EC - CERTIFICATE

Production Quality Assurance System

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

No. G2 08 04 66708 002

Manufacturer: **Medwell Medical Products Co.,Ltd.**

Fenglin Town, De An County
330400 Jiujiang City
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: **Shanghai International Holding Corp. GmbH (Europe)**

Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies): **Gauze Swab with / without X-Ray,
Lap Sponge without X-Ray,
Lap Sponge with X-Ray,
Lap Sponge with Barium Strip,
ABD Pad**

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.: SH08450CN

Valid until: 2011-12-27



Date, 2008-12-28

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. G2 08 04 66708 002

Facility(ies): Medwell Medical Products Co.,Ltd.
Fenglin Town, De An County, 330400 Jiujiang City,
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. G2S 09 10 66708 004

Manufacturer: **Medwell Medical Products Co.,Ltd.**

Fenglin Town, De An County
330400 Jiujiang City
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: **Shanghai International Holding Corp. GmbH (Europe)**

Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies): **Gauze Roll, Gauze Bandage, Cotton Wool Roll, Non-woven Sponge, Basic Dressing Pack, Surgical Gowns, Surgical Drapes**

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.: SH0945004

Valid until: 2011-12-27

Date, 2009-12-02

Hans-Heiner Junker



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 09 10 66708 004

Facility(ies): **Medwell Medical Products Co.,Ltd.**
Fenglin Town, De An County, 330400 Jiujiang City,
PEOPLE'S REPUBLIC OF CHINA



Product Service

CERTIFICATE

No. Q2N 09 10 66708 005

Holder of Certificate: **Medwell Medical Products Co.,Ltd.**

Fenglin Town, De An County
330400 Jiujiang City
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Medwell Medical Products Co.,Ltd.
Fenglin Town, De An County, 330400 Jiujiang City, PEOPLE'S
REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

**Production and Distribution of
Gauze Rolls, Gauze Bandages,
Cotton Wool Rolls, Non-woven Sponges,
Gauze Swabs, Lap Sponges, ABD Pads,
Basic Dressing Packs, Surgical Gowns,
Surgical Drapes**

**Applied
Standard(s):**

**EN ISO 13485:2003/AC:2007
ISO 13485:2003
Medical Devices - Quality Management Systems -
Requirements for regulatory purposes**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH0945004

Valid until: 2012-08-31

Hans-Heiner Junker

Date, 2009-12-02



Page 1 of 1

TÜV SÜD Product Service GmbH
Zertifizierstelle
Ridlerstraße 65 · 80339 München
Germany



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
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