



Product Service

EC Certificate

Production Quality Assurance

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 12 01 78540 003

Manufacturer:

**Changzhou Standard Medical
Devices Co., Ltd.**

Tongjiang Road

Xinbei District

213022 Changzhou, Jiangsu

PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

**Wellkang Ltd t/a Wellkang Tech
Consulting**

Suite B, 29 Harley Street

London

W1G 9QR

UNITED KINGDOM

Product Category(ies):

**Urine Drainage Bags, Vaginal Speculum,
Paediatric Urine Collector, Rectal Tube,
Sterile Latex Examination Gloves,
Sterile Absorbent Cotton,
Sterile Non-woven Sponge,
Sterile Lap Sponge, Sterile Gauze Swab**

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.:

SH1170201

Valid from:

2012-03-07

Valid until:

2017-03-06

Hans-Heiner Junker

Date, 2012-03-09



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

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Changzhou Standard Medical Devices Co., Ltd.
Tongjiang Road, Xinbei District, 213022
Changzhou, Jiangsu, PEOPLE'S REPUBLIC OF
CHINA