



Benannt durch/Designated by
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
 www.zlg.de
 ZLG-BS-244.10.08



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 002393 0014 Rev. 00

Manufacturer

Changshu Zengfu Medical Device Co., Ltd.

No.2 Zengfu Road
 Baimao Industrial Park
 Guli Town
 215532 Changshu City, Jiangsu Province
 PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
 EiffeustraÙe 80, 20537 Hamburg, GERMANY

Product

Category(ies):

**Urine Bag (with and without Gloves Pack/
 with and without Straps), Feeding Set,
 Urine Bag Infant, Vaginal Speculum,
 Specimen Container, Ear/Ulcer Syringe,
 Disposable Feminine Diagnostic Kit,
 Suture Remove Kits, Dressing Change Tray,
 Tracheostomy Care/Cleaning Kits, CPR Face Mask,
 Irrigation Tray, Prefilled Syringe, Suction
 Canister(Liner), Wet Skin Prep Tray, Forceps,
 Irrigation Syringe, Drainage Bag, Straps Set,
 Catheter Valve, IV Start Kit**

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.:

SH1985707

Valid from:

2019-06-04

Valid until:

2024-01-29

Date,

2019-06-04

Stefan Preiß

Head of Certification/Notified Body

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