

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 089714 0003 Rev. 02

Manufacturer

Changshu Kangbao Medical Appliance Factory

Furong Village, Baimao, Guli Town
215500 Changshu City, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Changshu Kangbao Medical Appliance Factory
Furong Village, Baimao, Guli Town, 215500 Changshu City,
Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

Changshu Leo Medical Appliance Co., Ltd
1# Furong Village, Baimao, Guli Town, 215500 Changshu City,
Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

**Urine Bag,
Enteral Feeding Set (Bag),
Disposable Enema Bag**

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.: SH19904EXT01

Valid from: 2019-06-06

Valid until: 2024-05-26

Date, 2019-06-06

I. Permit

Stefan Preiß
Head of Certification/Notified Body