



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 15 08 50651 031

Manufacturer:**Changshu SENLIN Medical
Appliance Co., Ltd.**No. 18 Zengfu Road
Baimao Industrial Park, Guli Town
215532 Changshu, Jiangsu
PEOPLE'S REPUBLIC OF CHINA**EC-Representative:****Shanghai International Holding
Corp. GmbH (Europe)**Eiffestraße 80
20537 Hamburg
GERMANY**Product
Category(ies):****Mucus Trap,
Urine Meters (w/wo Urine Sampling Blunt
Cannular), Feeding Set, Urine Bag Infant,
CPR Face Mask, Urine Bag (with and without
Gloves Pack/with and without Straps),
Straps Set, Catheter Valve**

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.:

SH15274EXT01

Valid from:

2015-10-28

Valid until:

2020-10-27

Hans-Heiner Junker

Date, 2015-09-16



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

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No. 18 Zengfu Road, Baimao Industrial Park, Guli
Town, 215532 Changshu, Jiangsu, PEOPLE'S
REPUBLIC OF CHINA