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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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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 045885 0019 Rev. 02

Manufacturer

**Jiangsu Shenli Medical
Production Co., Ltd.**

No. 20, Changzheng Rd, Zhenglu
Tianning District
213111 Changzhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Jiangsu Shenli Medical Production Co., Ltd.
No. 20, Changzheng Rd, Zhenglu, Tianning District, 213111
Changzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

**Sterile bladder irrigation sets for single use,
Sterile syringes without needles for single use,
Sterile irrigation syringes (feeding syringes) for single
use, Sterile infusion sets without needles for single use**

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.: SH19156EXT02

Valid from: 2019-09-27

Valid until: 2024-05-26

Date, 2019-09-27

Stefan Preiß
Head of Certification/Notified Body

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