



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 17 10 45084 035

Manufacturer:

**Wuxi Yushou Medical
Appliances Co., Ltd.**

No.215 Xigang Rd., Dongbeitang
214191 Wuxi/ Jiangsu
PEOPLE'S REPUBLIC OF CHINA



EC-Representative:

**Shanghai International Holding
Corp. GmbH (Europe)**

Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):

Infusion Sets without Needles, Sterile Hypodermic Syringe
for Single Use without Needles, Auto-disable Syringe
without Needles, Safety Syringe without Needles, Sterile
Vagina Dilator for Single Use, Disposable Connection Tube,
Needle for Reconstitution

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.:

SH17148EXT01

Valid from:

2018-01-20

Valid until:

2023-01-19

Date, 2017-11-17

Stefan Preiß



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

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No. G2S 17 10 45084 035**Facility(ies):**

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No.215 Xigang Rd., Dongbeitang, 214191 Wuxi/
Jiangsu, PEOPLE'S REPUBLIC OF CHINA

Wuxi Yushou Medical Appliances Co., Ltd.
Lot 95-B, Xishen Road, Wuxi New District, 214028
Wuxi, Jiangsu Province, PEOPLE'S REPUBLIC OF
CHINA