



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 080946 0007 Rev. 02

Manufacturer:

Anji SPENQ Industrial Co., Ltd.

F16, Building C
Anji Chamber of Commerce Mansion
No. 99 Tianhuangping South Road
313300 Anji County, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Anji SPENQ Industrial Co., Ltd.
F16, Building C, Anji Chamber of Commerce Mansion, No. 99
Tianhuangping South Road, 313300 Anji County, Zhejiang
Province, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

**Latex Foley Catheters, Oxygen Masks, Sterile Blood
Lancets, Sterile Latex Surgical Gloves, Sterile Syringes
for Single Use, Sterile Infusion Sets for Single Use,
Sterile Intravenous Needles for Single Use, Sterile
Hypodermic Needles for Single Use, Sterile Blood
Transfusion Sets for Single Use, Nasal Oxygen
Cannulaes, Suction Catheters, Stomach Tubes, Feeding
Tubes, Nelaton Catheter, Disposable Surgical Blades,
Endotracheal Tubes, Laryngeal Mask, Reinforced
Endotracheal Tube, Mucus Extractor, Tracheostomy
Tube, Silicone Foley Catheter**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.:

SH1960110

Valid from:

2019-11-13

Valid until:

2020-11-23

Date,

2019-11-13

Christoph Dicks
Head of Certification/Notified Body