DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q6 080946 0012 Rev. 01

Digitally signed by Jighili Tatiana
Date: 2023.09.15 18:52:01 EEST
Reason: MoldSign Signature
Location: Moldova

Holder of Certificate: **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

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Production and Distribution of Medical Dressings, Medical Disposable Products and Medical Instruments**

Applied Standard(s):
EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1960110

Valid from: 2019-11-24
Valid until: 2022-11-23

Date, 2019-11-13

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
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 080946 0010 Rev. 03

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):

Disposable Vaginal Speculums, Disposable Colostomy Bags, Disposable Vaginal Irrigation Sets, Urine Bags, Umbilical Cord Clamps, Sterile Latex Examination Gloves, Wound Plasters, Liquid Transfusion Plasters, Adhesive Wound Dressings, First-Aid Kits, Sterile Gauze Sponges, Rectal Tubes, Skin Closure Strips, Surgical Drapes, Sterile Surgical Gown, Absorbent Cotton Rolls, Absorbent Cotton Balls, Absorbent Cotton Pads, Eye Pad, Abdominal Pads, Non-woven Swabs, Lap Sponge, Gauze Roll

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.: SH19601EXT01

Valid from: 2020-01-29

Valid until: 2024-05-26

Date, 2020-01-29

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
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www.zlg.de
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 IIa, IIb or III)

No. G2 080946 0007 Rev. 03

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.: SH19601EXT01

Valid from: 2020-01-29

Valid until: 2024-05-26

Date, 2020-01-29

Christoph Dicks
Head of Certification/Notified Body

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