Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD 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. 01

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

EC-Representative:

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE Amsterdam, THE NETHERLANDS

Product Category(ies):

Latex Foley Catheters, Oxygen Masks, Sterile Blood Lancets, Sterile Latex Surgical Gloves, Digital Thermometers, Blood Pressure Monitors, 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.: SH1860109

Valid from: 2018-12-03
Valid until: 2020-11-23

Date, 2018-12-03

Stefan Preis

Digitally signed by Chitic Ecaterina
Date: 2019.04.04 19:20:19 EEST
Reason: MoldSign Signature
Location: Moldova

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

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(Devices in Class IIa, IIb or III)

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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

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

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