ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 16 08 80946 007

Manufacturer:

Anji SPENQ Industrial Co., Ltd.
Tangpu Economic Development Zone
313300 Anji City, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

SUNGO Certification Company Limited
RM101, MAPLE HOUSE
118 HIGH STREET, PURLEY
LONDON
CR8 2AD
UNITED KINGDOM

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.: SH1660107

Valid from: 2016-12-20
Valid until: 2020-11-23

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Date, 2016-12-20

Stefan Preiß

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

Digitally signed by Chitic Ecaterina
Date: 2019.02.25 14:55:26 EET
Reason: MoldSign Signature
Location: Moldova

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Facility(ies):

Anji SPENQ Industrial Co., Ltd.
Tangpu Economic Development Zone, 313300 Anji City, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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