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

Product Service

CERTIFICATE

No. Q6 077224 0007 Rev.

Holder of Certificate: **Suzhou Yaxin Medical Products Co., Ltd.**
No.12, Zhongta Road, Mudu Town
215101 Suzhou
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):
Suzhou Yaxin Medical Products Co., Ltd.
No.12, Zhongta Road, Mudu Town, 215101
Suzhou, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

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

Scope of Certificate:
Production and Distribution of
Disposable Nasal Oxygen Cannula,
Disposable Suction Connecting Tube,
Disposable Urinary Catheter,
Disposable Suction Catheter,
Disposable Gastric Tube,
Disposable Feeding Bag,
Disposable Urine Drainage Bag,
Disposable Chest Drainage Bottle,
Disposable Oxygen Mask

Applied Standard(s):
EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

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.: SH1670104

Valid from: 2019-12-12
Valid until: 2022-12-11

Date, 2019-12-12

Stefan Preiß

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

TÜV®

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 077224 0005 Rev. 00

Manufacturer

Suzhou Yaxin Medical Products Co., Ltd.
No.12, Zhongta Road, Mudu Town
215101 Suzhou
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

Product Category(ies):

Disposable Feeding Bag,
Disposable Urine Drainage Bag,
Disposable Chest Drainage Bottle

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.: SH18701EXT01

Valid from: 2018-12-12
Valid until: 2023-12-11

Date, 2018-09-28

Stefan Preiß

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