



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:

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

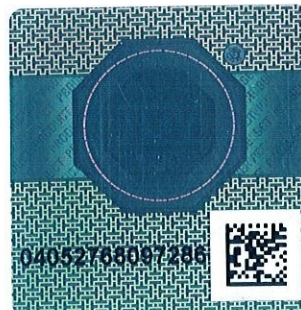
Valid from: 2019-12-12

Valid until: 2022-12-11

Date, 2019-12-12

Stefan Preiß

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



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 0009 Rev. 00

Manufacturer

Suzhou Yaxin Medical Products Co., Ltd.

No.12, Zhongta Road, Mudu Town
215101 Suzhou
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Prolinx GmbH
Brehmstr. 56, 40239 Duesseldorf, 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.:

SH1870106

Valid from:

2019-07-02

Valid until:

2023-12-11

Date,

2019-07-02

Stefan Preiß
Head of Certification/Notified Body

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 0009 Rev. 00

Facility(ies):

Suzhou Yaxin Medical Products Co., Ltd.

No.12, Zhongta Road, Mudu Town, 215101 Suzhou, PEOPLE'S
REPUBLIC OF CHINA

Declaration of Conformity

Manufacturer: Suzhou Yaxin Medical Products Co., Ltd.

No.12, Zhongta Road, Mudu Town, 215101 Suzhou, P.R.China

European Representative: Prolinx GmbH

Brehmstr. 56, 40239 Duesseldorf, GERMANY

Product Name: Disposable Feeding Bag

Model Number: 1200ml, Catalog code: 04020102

GMDN code: 11675

Classification (MDD, Annex IX): I, Rule 1

Conformity Assessment Route: Annex V.3

We declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. Manufacturer is exclusively responsible for the declaration of conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 2007/47/EEC concerning medical devices (MDD 2007/47/EEC).

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany

NB Identification number: 0123

(EC) Certificate(s): G2S 0772240009 Rev.00

Expire date of the Certificate: 2023-12-11

Start of CE Marking: not until now

Place, Date of Issue: Suzhou, 2019-07-02

Signature: _____

Name: Mr. Zhang WeiFang

Position: General Manager

