

Suzhou Yaxin Medical Products Co.,Ltd CE Technical File		Document Number
Product	Disposable Suction Connecting Tube	SZYX/9.1-02(B)-02-2014
Title	Declaration of Conformity	Page 1 of 4

1 Overview

According to the EU “Medical Devices Directive” requirements, the corporation and the authorized European Representative promise, ensure and declare that all the referred products comply with MDD requirements.

2 Information about manufacturer

Name: SuzhouYaxin Medical Products Co., Ltd.

Address: No.12, Zhongta Road, Mudu Town, Suzhou

Zip code: 215101

3 Information about the authorized European Representative

Name: Prolinx GmbH

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Address: Room 301, No 815, Dongdaming Road, Hongkouarea, Shanghai, China

Zip code: 200082

4 Product name: Disposable Suction Connecting Tube

5 Model: Fr24, 26, 28, 30, 32, 34, 36, with/without Yankauer handle

6 Classification: Class II a, sterile Rule 7

7 The contents of the statement

We declare that the above-mentioned products meet the provisions of the following EC Council Directives and Standards (2007/47/EEC), and All products conform to the intended use. All the supporting documentations are proved and we promise its authenticity. Assessment route is V.3.

8 General applicable directives

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

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9 Executive Standard

EN ISO13485 EN ISO14971 ISO14155 EN ISO11135
BS EN ISO 15223-1 EN ISO10993 series ISO11607-1, 2 EN1041
EN ISO11737-1, 2 EN ISO 14698-1,2

10 Notified Body and code

Name: TÜV Product Service GmbH, Ridlerstr.65,80339München,Germany

Code:0123

11 Certificate No: G2 07 7224 0008

12 Release Date and place

Date: 2019.07.02

Place: Suzhou, Jiangsu, China

13 Release people, Position and Signature

Release people (Signature):

Position: General Manager

14 Annex

Annex 1: Declaration of Compliance (sample)

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Declaration of Conformity

Manufacturer: Suzhou Yaxin Medical Products Co., Ltd.

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

European Representative: Shanghai International Holding Corp. GmbH (Europe)

Eiffestrasse 80, 20537 Hamburg, Germany

Product Name: Disposable Suction Connecting Tube

Model Number: Fr24, 26, 28, 30, 32, 34, 36 with/without Yankauer handle

UMDNS Code: 14188

Classification (MDD, Annex IX): II a, Rule 7

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

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(EC) Certificate(s): G2 0772240008

Expire date of the Certificate: 2019-07-02

Start of CE Marking: not until now

Place, Date of Issue: Suzhou, 2023-12-11

Signature: _____

Name: Mr. Zhang WeiFang

Position: General Manager
