

Declaration of Conformity

Manufacturer name: Wuxi Yushou Medical Appliances Co., Ltd

Manufacturer address: No.215 Xigang Rd., Dongbeitang 214191, Wuxi/Jiangsu, PEOPLE'S REPUBLIC OF CHINA
Lot 95-B, Xishen Road, Wuxi New District, 214028 Wuxi/Jiangsu, PEOPLE'S REPUBLIC OF CHINA

EC-Representative name: Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Product name: Sterile Syringe for High Pressure CT, DSA, MRI Angiography Use and Disposable Connection Tube

Classification: Rule 6, II a and and I

Models: 12ml, 20ml, 30ml, 50ml, 60ml, 65ml, 100ml, 115ml, 125ml, 130ml, 140ml, 150ml, 200ml and CT 150cm, T 150cm, Y 150cm, Y 255cm, Multi way connection tube(pump hose), Outer Lines

Conformity assessment route: MDD Annex VII+V

We declare that:

the above mentioned CE marked products meet the provisions of the following EC Council Directives. All technical documentations are retained under the promise of the manufacturer.

Directives

COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES (MDD 93/42/EEC), AMENDED BY 2007/47/EC OF 5 SEPTEMBER 2007.

Notified Body Name: TUV SUD Product Service GmbH

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Code: 0123

CE Certificate No.: G2 045084 0034 Rev.01 and G2S 17 10 45084 035

CE mark starting batch or date: 2018.01.20

Period of validity: The validity period of this declaration of conformity is limited by the issuing of a revised declaration of conformity after change of the product and/or by the expiration date of the related Annex II certificate issued by the notified body.

Wuxi Yushou Medical Appliances Co.Ltd

Date:2018.01.20

