

山东五洲医疗器械有限公司

SHANDONG WUZHOU MEDICAL EQUIPMENT CO.,LTD.
(Yantai)Industrial park, Dingtao country, Shandong province, China

EC DECLARATION OF CONFORMITY

We Shandong Wuzhou Medical Equipment Co.,Ltd.

Hereby declare that the product, details of which are given below, is manufactured by us.

Manufacturer: Shandong Wuzhou Medical Equipment Co.,Ltd.

Add: Dingtao(Yantai)Industrial Area, Heze, 274100 Shandong, P.R. China.

European Authorized Representative info:

Company: Lotus NL B.V.

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

E-mail: peter@lotusnl.com

Tel: +31644168999

Product:

- Disposable syringe with needles
- Infusion sets (drip chamber, luer lock, latex, needle, tube ...)
- Blood transfusion Set
- Insulin syringe
- Hypodermic needle
- Intravenous Needle
- Sterile Self-destruction safety syringes for single use
- Safety blood collection needles for single use
- Intravenous infusion sets with burette
- Hemodialysis Blood tubing set
- Disposable dental needles
- Sterile lancets for single use
- Insulin pen needles
- Extension line

Product Classification (Annex IV of MDD Directives): IIa

UMDNS Code: 17984

CE ID No. : 0197

Conformity assessment route: Annex V、VII

Refer standards : ISO 13485:2016

We here with declare that the above mentioned products meet the provisions of the council directive 93/42/EEC Amended by 2007/47/EC for medical devices.

All supporting documentation is retained under the premises of the manufacturer.

Notified body: TUV Rheinland LGA Products GmbH

Registration No: DD 2027188-1

Start of CE marking: 2021-05-13

General Manager: Zhang Wen

Quality System Manager: Wang Lijuan

Shandong Wuzhou Medical Equipment Co., Ltd.

山东五洲医疗器械有限公司

中国 山东
CHINA SHANDONG

Zhang Wen