



Declaration of Conformity

Manufacturer: Anhui Hongyu Wuzhou Medical Manufacturer Co.,Ltd
Address: No.2 Guanyin Road ,Economic Development Zone,Taihu County
246400,Anqing,Anhui,PEOPLE'S REPUBLIC OF CHINA
Tel.:0556-4248888; **Fax:**0556-4249999;**Post:**246400

AUTHORIZED EUROPEAN REPRESENTATIVE

Name: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg, Germany
Tel:0049-40-2513175; **Fax:**0049-40-255726

Medical Device:

-Name of Products: Sterile hypodermic syringes for single use ; Sterile hypodermic needles for single use ; Sterile insulin syringes for single use ; Insulin pen-injectors for medical use ; Transfusion sets for single use ; Infusion sets for single use(gravity feed) ; Burette-type infusion sets for single use ; Intravenous needles for single use ; Blood collection needles for single use ; Sterile dental injection needles for single use; Disposable precision flow regulator; insulin pen needle for single use; Blood collection set for single use; Sterile safety hypodermic needle for single use; Safety blood collection set for single use; Safety blood collection needle for single use.

-Classification: IIa

Conformity evaluation

My company production of Sterile syringes for single use with needles; Sterile hypodermic needles for single use; Sterile insulin syringes for single use; Insulin pen-injectors for medical use; Transfusion sets for single use ; Infusion sets for single use(gravity feed); Burette-type infusion sets for single use; Intravenous needles for single use; Blood collection needles for single use; Sterile dental injection needles for single use; Disposable precision flow regulator; insulin pen needle for single use; Blood collection set for single use; Sterile safety hypodermic needle for single use; Safety blood collection set for single use; Safety blood collection needle for single use, which belongs to a product IIa, According to the 93/42/EEC declaration of conformity procedure to select the authentication way , additional CE mark.

General applicable directives: COUNCIL DIRECTIVE (MDD93/42/EEC).

Notified Body: TÜV SÜD Product Service GmbH 0123

GMDN CODE : Sterile Syringe for single use with needle:35904

Wuzhou
Medical
五洲·医疗器械



安徽宏宇五洲医疗器械股份有限公司

Anhui Hongyu Wuzhou Medical Manufacturer Co.,Ltd

Add:No.2 Guanyin Road ,Economic Development Zone,Taihu County 246400,Anqing,Anhui,PEOPLE'S REPUBLIC OF CHINA

EC Certificate(s):

NO. G2 081232 0010 Rev.02

ANHUI HONGYU WUZHOU MEDICAL MANUFACTURER CO., LTD.

Issue date: 2020-03-03

安徽宏宇五洲医疗器械股份有限公司

Address: No.2 Guanyin Road ,Economic Development Zone,Taihu County
246400,Anqing,Anhui,PEOPLE'S REPUBLIC OF CHINA

General Manager: ZHANG HONGYU

Date: 18th, JAN, 2023