

# 安徽宏宇五洲医用器材有限公司

## ANHUI HONGYU WUZHOU MEDICAL MANUFACTURER CO., LTD.

### Declaration

Date: 2016/03/28

#### Products

Name: Disposable Syringe

Model: 2cc 23G x 1 1/2", 5cc 21G x 1 1/2", 10cc 21G x 1 1/2", 20cc 20G x 1 1/2"

Batch No.: 160225

Quantity: 2cc 23G x 1 1/4" 372,000pcs; 5cc 21G x 1 1/2" 312,000pcs;

10cc 21G x 1 1/2" 320,000pcs; 20cc 20G x 1 1/2" 116,000pcs;

Name: Transfusion Set

Model: Luer Lock Batch No.: 160302

Quantity: Luer Lock 15,200pcs

We hereby declare the above products that distributed by Wenzhou Wuzhou Imp. & Exp. Co., Ltd. is manufactured by us Anhur Hongyu Wuzhou Medical Manufacturer Co., Ltd.

Mr.Zhang Hongyu

Legal Representative

Anhui Hongyu Wuzhou Medical Manufacturer Co., Ltd.

No.2, Guanyin Road, Economic Development Zone, Taihu 246400, Anhui, China.



### ANHUI HONGYU WUZHOU MEDICAL MANUFACTURER CO.,LTD.

No.2 Guanyin Road, Economy Development Zone Taihu, Anhui, China.

#### EC DECLARATION OF CONFORMITY

EC Declaration of conformity relating to the following medical device

MANUFACTURER:

Name: Anhui Hongyu Wuzhou Medical Manufacturer Co., Ltd.

Address: No.2 Guanyin Road Economic Development Zone Taihu County

246400 Anging, Anhui PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Name: Shanghai International Holding Corp.GmbH(Europe)

Address: EiffestraBe 80 20537 Hamburg GERMANY

#### MEDICAL DEVICE:

Product Description	Class	GMDN Code
Sterile hypodermic syringes for single use	IIa	12132
Sterile hypodermic needles for single use	IIa	12745
Blood collection needles for single use	Па	35209
Transfusion sets for single	Па	33172

The undersigned hereby declares that the product concerned has been designed and manufactured under a quality management system according to Annex V of directive MDD 93/42/EEC. Compliance of the designed product with the Directive 93/42EEC has been assessed and certified by the Notified Body.

NOTIFIED BODY: TUV SUD Product Service Gmbh

Address: Zertifizierstelle, Ridlerstraße 65,80339 Munchen, Germany.

Identification No.: 0123

EC certificate(s) No.: G2 14 07 81232 004

Place, Date of Issue : Anhing China on 2014, 12.05

Signature and Stamp