



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 081232 0010 Rev. 02

Manufacturer:

**AnHui Hongyu Wuzhou
Medical Manufacturer Co.,Ltd.**

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

**Product
Category(ies):**

**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
Needles for Single Use, Blood Collection Sets for Single Use,
Sterile Safety Hypodermic Needles for Single Use, Safety
Blood Collection Sets for Single Use, Safety Blood Collection
Needles for Single Use**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH19735EXT01

Valid from: 2020-03-03

Valid until: 2024-05-26

Date, 2020-03-03

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17



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

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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