DECLARATION of CONFORMITY
to Council Directive 93/42/EEC of 14 June 1993
concerning medical devices as amended by 2007/42/EC

Manufacturer:	SHANDONG WUZHOU MEDICAL EQUIPMENT Co., Ltd. DINGTAO COUNTY (YANTAI)INDUSTRIAL ZONE HEZE CI TY 274100 SHANDONG CHINA
Medical Device:	**Infusion Set for single use**
Classification-Annex IX:	**CLASSIIa, RULE7**
Conformity Assessment Route:	Annex II.3

We, SHANDONG WUZHOU MEDICAL EQUIPMENT Co., Ltd. Herewith declare that the stated medical devices meet the transposition into national law, the provisions of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices as amended by 2007/42E E C; All supporting documentation is retained at the premises of the manufacturer.

Notified Body:	TÜV Rheinland Lga Products GmbH. Tilystrase 2 – 90431 Nürnberg
Identification Number	CE 0197
(EC) Certificate(s)	DD 601500620001
EC REP European Representative:	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Start of CE-Marking 2016.09.05

Place, Date of Declaration: June,29.2020

Signature:

Name: ZHANG WEN

Position: GENERAL MANAGER

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60150062 0001

Report No.: 16806396 009

Manufacturer:
SHANDONG WUZHOU MEDICAL
EQUIPMENT CO., LTD.
DINGTAO COUNTY (YANTAI)
INDUSTRIAL ZONE
HEZE CITY
274100 Shandong
P.R. China

Products: Medical Devices

(See attachment for Products included)

Repalces Approval, Registration No.: DD 60145714 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2020-06-29

Date: 2020-06-29

Notified Body
TÜVRheinland LGA Products GmbH

Jing Zhang

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60150062 0001
Report No.: 16806396 009

Manufacturer:
SHANDONG WUZHOU MEDICAL
EQUIPMENT CO., LTD.
DINGTAO COUNTY (YANTAI)
INDUSTRIAL ZONE
HEZE CITY
274100 Shandong
P.R. China

Products:

- Disposable Syringe with Needles
- Infusion Sets
- Blood Transfusion Sets
- Insulin Syringes
- Hypodermic Needles
- Intravenous Needles
- Sterile Self-destruction Safety Syringes for Single Use
- Safety Venous Blood Collection Needles
- Intravenous Infusion Sets with Burette
- Hemodialysis Blood Tubing Sets
- Disposable Dental Needles

Aspects of Manufacture Concerned with Securing and Maintaining Sterile Conditions:

- Drainage Bags
- Vaginal Dilators
- Sterile Dental Irrigation Syringes
- Sterile Dental Irrigation Needle Tips

TÜV Rheinland LGA Products GmbH TÜVRheinland

Notified Body

Date: 2020-06-29

Jing Zhang