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

TÜV SÜD 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 094558 0005 Rev. 01

Digitally signed by Neer Ghennadii
Date: 2023.08.04 09:09:12 EEST
Reason: MoldSign Signature
Location: Moldova

Manufacturer:

Jiangyin Fanmei Medical Device Co., Ltd.
No.19 Yishan Rd, Lingang Street
214400 Jiangyin
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

**Infusion Sets with Needles,Intravenous Needles,
Safety Syringe,
Auto-disable Syringe,
Disposable Blood Transfusion Sets,
Sterile Surgical Gloves,
Feeding Tube, Stomach Tube,
Suction Catheter, Nelaton Tube,
Nasal Oxygen Cannula, Oxygen Mask,
Disposable Blood Collection Needles,
Syringe for Insulin, Sterile Syringe for Single Use (with Needle),
Sterile Hypodermic Needle 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.: SH191005EXT01

Valid from: 2020-01-07
Valid until: 2024-05-26

Date, 2020-01-07

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
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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 094558 0005 Rev. 01

Facility(ies):

Jiangyin Fanmei Medical Device Co., Ltd.
No.19 Yishan Rd, Lingang Street, 214400 Jiangyin,
PEOPLE'S REPUBLIC OF CHINA

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

TÜVRheinland®

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2319673-1

Organization: Shandong Qinkai Medical Industry Co., Ltd.
(South Section of Quancheng Road in Industrial Park) Medical Equipment Industrial Park, Chengwu County, Heze, 274200 Shandong, P.R. China

Scope: Manufacturing and Distribution of Disposable Infusion Sets, Disposable Syringes with Needles, Disposable Blood Transfusion Sets, Disposable Burette Infusion Sets, Scalp Vein Sets, Urine Bags, Surgical Face Masks

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 190130294 120
Effective date: 2021-04-23
Expiry date: 2024-04-22
Issue date: 2021-04-23

TÜV Rheinland LGA Products GmbH

Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-14169-01-02

TÜVRheinland®

EC Certificate

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

Registration No.: DD 2319673-1

Manufacturer: Shandong Qinkai Medical Industry Co., Ltd.
(South Section of Quancheng Road in Industrial Park) Medical Equipment Industrial Park, Chengwu County, Heze, 274200 Shandong, P.R. China

Products: Disposable Infusion Sets, Disposable Syringes with Needles, Disposable Blood Transfusion Sets, Disposable Burette Infusion Sets, Scalp Vein Sets

For the following medical devices the scope covers the aspects of manufacture concerned with securing and maintaining sterile conditions: Urine Bags, Surgical Face Masks

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.

Report No.: 190130294 120

Effective date: 2021-04-23

Expiry date: 2024-05-26

Issue date: 2021-04-23

TÜV Rheinland LGA Products GmbH

ding Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

Declaration of conformity

a. Manufacturer

Manufacturer name: Jiangyin Fanmei Medical Device Co., Ltd.

Manufacturer address: No.19 Yishan Rd, Lingang Street, 214400 Jiangyin, People's Republic of China

Tel: 0086-510-86688750 Fax: 0086-510-86688750 E-mail: info@fmsyringe.com

b. EC-representative

EC-representative name: ZOUSTECH S.L.

EC-representative address: Pso. Castellana, 141 - Planta 19, 28046 - Madrid, Spain

Tel: +34694426446 Fax: +34917915466 E-mail: legal@zoustech.eu

c. Product name: Syringe for Insulin

d. UMDNS Code of product: 13941

e. Classification of product: MDD 93/42/EEC Class IIa (Rule 6)

f. Conformity assessment route: MDD 93/42/EEC Annex V.3

g. We declare:

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the promises of the manufacturer. Our company is exclusively responsible for this Declaration of Conformity.

h. We follow the applicable directives include:

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC

i. Notified body

Notified Body name: TUV SUD Product Service GmbH

Notified Body address: Ridlerstr65 Munich 80339, Germany

Identification number: 0123

Certificate No.: G20945580005 Rev.01

Valid until 2024-05-26

CE-marking starting batch or date: 2016-10-8

Signature of issuing person:

Name: Weijun Shao

Title: General Manager

Location: Jiangyin, China

FINE MED

江阴市泛美医疗器械有限公司

JIANGYIN FANMEI MEDICAL DEVICE CO.,LTD

TEL:86-510-86688750 FAX:86-510-86688750

Declaration of conformity

a. Manufacturer

Manufacturer name: Jiangyin Fanmei Medical Device Co., Ltd.

Manufacturer address: No.19 Yishan Rd, Lingang Street, 214400 Jiangyin, People's Republic of China

Tel: 0086-510-86688750 Fax: 0086-510-86688750 E-mail: info@fmsyringe.com

b. EC-representative

EC-representative name: ZOUSTECH S.L.

EC-representative address: Pso. Castellana, 141 - Planta 19, 28046 - Madrid, Spain

Tel: +34694426446 Fax: +34917915466 E-mail: legal@zoustech.eu

c. Product name: Sterile Syringe for Single Use (with Needle)

d. UMDNS Code of product: 13929

e. Classification of product: MDD 93/42/EEC Class IIa (Rule 6)

f. Conformity assessment route: MDD 93/42/EEC Annex V.3

g. We declare:

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the promises of the manufacturer. Our company is exclusively responsible for this Declaration of Conformity.

h. We follow the applicable directives include:

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC

i. Notified body

Notified Body name: TUV SUD Product Service GmbH

Notified Body address: Ridlerstr65 Munich 80339, Germany

Identification number: 0123

Certificate No.: G2 094558 0005 Rev.01

Valid until 2024-05-26

CE-marking starting batch or date:2016-10-18

Signature of issuing person:

Name: Weijun Shao

Title: General Manager

Location: Jiangyin, China

JIANGYIN FANMEI MEDICAL DEVICE CO.,LTD 江阴市泛美医疗器械有限公司

TÜVRheinland®

EC Certificate

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

Registration No.: DD 2319673-1

Manufacturer: Shandong Qinkai Medical Industry Co., Ltd.
(South Section of Quancheng Road in Industrial Park) Medical Equipment Industrial Park, Chengwu County, Heze, 274200 Shandong,
P.R. China

Products: Disposable Infusion Sets, Disposable Syringes with Needles, Disposable Blood Transfusion Sets, Disposable Burette Infusion Sets, Scalp Vein Sets

For the following medical devices the scope covers the aspects of manufacture concerned with securing and maintaining sterile conditions:
Urine Bags, Surgical Face Masks

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.

Report No.: 190130294 120

Effective date: 2021-04-23

Expiry date: 2024-05-26

Issue date: 2021-04-23

TÜV Rheinland LGA Products GmbH

ding Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

TÜVRheinland®

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.:	SX 2319673-1
Organization:	Shandong Qinkai Medical Industry Co., Ltd. (South Section of Quancheng Road in Industrial Park) Medical Equipment Industrial Park, Chengwu County, Heze, 274200 Shandong, P.R. China
Scope:	Manufacturing and Distribution of Disposable Infusion Sets, Disposable Syringes with Needles, Disposable Blood Transfusion Sets, Disposable Burette Infusion Sets, Scalp Vein Sets, Urine Bags, Surgical Face Masks

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.:	190130294 120
Effective date:	2021-04-23
Expiry date:	2024-04-22
Issue date:	2021-04-23

TÜV Rheinland LGA Products GmbH

Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Shandong Qinkai Medical Industry Co.,Ltd.

(South Section of Quancheng Road in Industrial Park) ,Medical Equipment Industrial Park,Chengwu County,Heze,274200 Shandong,P.R.China

EC DECLARATION OF CONFORMITY

Manufacturer's Name:	:Shandong Qinkai Medical Industry Co.,Ltd.
Manufacturer's Address:	:(South Section of Quancheng Road in Industrial Park) ,Medical Equipment Industrial Park,Chengwu County,Heze,274200 Shandong,P.R.China
Name of Device	: Dispossable Blood Transfusion Sets
Classification	: Class lla
Conformity Assessment Procedure	: EC Declaration of conformity set out in Annex V
Conformity Route	: Self Declaration

We herewith declare that the above mentioned products meet the prow visions of the council Directive 93/42/EEC for medical devices.All supporting documentation is retained under the promises of manufacturer

Quality Management System	: EN ISO 13485:2012 + AC:2012
Notified Body Name/Address	: TUV Rheinland LGA Products GmbH Tillystraβe 2 – 90431 Nurnberg
Registration No	:DD 2319673-1
Registration Date	:2021-04-23
Cert valid Until	:2024-05-26
Issue Date	:2021-04-23
Stamp /signature	:

Shandong Qinkai Medical Industry Co.,Ltd.
(South Section of Quancheng Road in Industrial Park) ,Medical Equipment Industrial Park,Chengwu County,Heze,274200 Shandong,P.R.China

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: /
Name and address of the manufacturer: /
Nom et adresse du fabricant: /
Nome e indirizzo del fabbricante:

**Shandong Qinkai Medical Industry Co., Ltd.
(South Section of Quancheng Road in Industrial Park)
Medical Equipment Industial Park, Chengwu County,
Heze, 274200, Shandong Province, P.R.China**

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /
Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: /
the medical device: /
le dispositif médical: /
il dispositivo medico:

Disposable Infusion Sets

der Klasse: /
of class: /
de la classe: /
di classe:

Class IIa

nach Anhang IX der Richtlinie 93/42/EWG / according to annex IX of directive
93/42/EEC /
selon l'annexe IX de la directive 93/42/CEE / secondo l'allegato IX della direttiva
93/42/CEE

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 93/42/EWG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll". /
meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l'inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 93/42/CEE e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il "rapporto di ispezione finale" del prodotto.

Konformitätsbewertungsverfahren: /
Conformity assessment procedure: /
Procédure d'évaluation de la conformité: /
Procedura di valutazione della conformità:

Directive 93/42/EEC Annex V

Registrier-Nr.: /
Registration No.: /
N°d'enregistrement: /
Numero di registrazione:

**Certificate No.: SX 2319673-1
Issue date:2021-04-23
Expiry date:2024-04-22**

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

**TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Deutschland
CE 0197**

SHANDONG QINKAI MEDICAL INDUSTRY CO.,LTD. 3717230014509

Heze 2021-06-22
Ort, Datum / Place, date /
Lieu, date / Luogo, data

GM: 姜鸥凯
Name und Funktion / Name and function /
Nom et fonction / Nome e funzione