



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 094558 0005 Rev. 01

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



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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**

Declaration of Conformity

Manufacturers

Suzhou Hengxiang Import & Export Co., Ltd.
18F., 1638 Xi Huan Road, 215004, Suzhou, PEOPLE'S REPUBLIC OF CHINA

European Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

Product Name: Surgical Gloves

UMDNS Code: 11883

Product Classification: IIa, rule 7

Product compatibility certification means: MDD Appendix V .3+VII

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 premises of the manufacturer.

DIRECTIVES

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC concerning medical devices (Amended by 2007/47/EC).

Notified Body: TÜV Product Service GmbH, Ridlerstr. 65, 80339 München, Germany

Identification number: CE0123

(EC) Certificate(s): G2120243199015

Expire date of the Certificate: 2022-06-13

Start of CE Marking: 2005-12-01.

Place, Date of Issue: Suzhou, China 2020-09-12

Signature: _____

Name: Mark Ho

Position : Deputy General Manager

苏州恒祥进出口有限公司

SUZHOU HENG XIANG IMPORT & EXPORT CO., LTD.

10/F., 888 CHENGHU ROAD, WUZHONG, SUZHOU 215168, JIANGSU, P. CHINA

FAX: 0086 512 6826 8112 TEL: 0086 512-6862 9896 E-MAIL: suhoma@hotmail.com

Technical Specifications

Product Name:	Latex Surgical Gloves
Class:	IIa
Size:	6" / 6.5" / 7" / 7.5" / 8" / 8.5" / 9"
Type:	Powder-free
Color:	Natural
Length:	6"/6.5"/7" $\geq 260\text{mm}$ 7.5" $\geq 270\text{mm}$ 8.5"/9" $\geq 280\text{mm}$
Width of Palm:	6" $\geq 77\text{mm} \pm 5\text{mm}$ 6.5" $\geq 83\text{mm} \pm 5\text{mm}$ 7" $\geq 89\text{mm} \pm 5\text{mm}$ 7.5" $\geq 95\text{mm} \pm 5\text{mm}$ 8" $\geq 102\text{mm} \pm 6\text{mm}$ 8.5" $\geq 108\text{mm} \pm 6\text{mm}$ 9" $\geq 116\text{mm} \pm 6\text{mm}$
Thickness:	Finger tip $\geq 0.017\text{mm}$ Palm $\geq 0.015\text{mm}$ Cuff $\geq 0.013\text{mm}$
Tensile Strength:	24Mpa before aging 18Mpa after aging
Elongation:	700% before aging 550% after aging
Pin Hole:	$\leq \text{AQL}1.5$
Sterilization:	Gamma Raidation
Packaging:	Individually wrapped by paper wallet /paper sterile pouch
Packing:	50 Pairs / Paper Box

Prepared by: Zhu Yong; Checked by: Helen Xu; Approved by: Mark Ho

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Produsator	Reprezentant	Ordin	Data
DM0000002801	MĂNUȘI CHIRURGICALE DIN LATEX		PUDRATE, MĂRIMEA 3		China	SUZHOU HENGXIANG IMPORT & EXPORT CO., LTD.	I.M. BECOR S.R.L.	A07/PS-01.Rg04-101	15-05-2015
DM0000002800	MĂNUȘI CHIRURGICALE DIN LATEX		PUDRATE, MĂRIMEA 8,5		China	SUZHOU HENGXIANG IMPORT & EXPORT CO., LTD.	I.M. BECOR S.R.L.	A07/PS-01.Rg04-101	15-05-2015
DM0000002798	MĂNUȘI CHIRURGICALE DIN LATEX		PUDRATE, MĂRIMEA 7,5		China	SUZHOU HENGXIANG IMPORT & EXPORT CO., LTD.	I.M. BECOR S.R.L.	A07/PS-01.Rg04-101	15-05-2015
DM0000002797	MĂNUȘI CHIRURGICALE DIN LATEX		PUDRATE, MĂRIMEA 7		China	SUZHOU HENGXIANG IMPORT & EXPORT CO., LTD.	I.M. BECOR S.R.L.	A07/PS-01.Rg04-101	15-05-2015
DM0000002795	MĂNUȘI CHIRURGICALE DIN LATEX		PUDRATE, MĂRIMEA 6		China	SUZHOU HENGXIANG IMPORT & EXPORT CO., LTD.	I.M. BECOR S.R.L.	A07/PS-01.Rg04-101	15-05-2015
DM0000002799	MĂNUȘI CHIRURGICALE DIN LATEX		PUDRATE, MĂRIMEA 8		China	SUZHOU HENGXIANG IMPORT & EXPORT CO., LTD.	I.M. BECOR S.R.L.	A07/PS-01.Rg04-101	15-05-2015
DM0000002796	MĂNUȘI CHIRURGICALE DIN LATEX		PUDRATE, MĂRIMEA 6,5		China	SUZHOU HENGXIANG IMPORT & EXPORT CO., LTD.	I.M. BECOR S.R.L.	A07/PS-01.Rg04-101	15-05-2015