DAkkS
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Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q6 056464 0019 Rev. 03

Holder of Certificate: **Jiangsu Webest Medical Product Co., Ltd.**
No.5 Yingchun Rd. Industrial park
211700 Xuyi, JiangSu
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Production and Distribution of Sterile Infusion Sets for Single Use, Sterile Syringes for Single Use, Sterile Three-Way Stopcocks for Single Use, Sterile Heparin Caps for Single Use, Sterile Dental Needles for Single Use, Scalp Vein Set for Single Use, I.V. Cannula for Single Use, Hypodermic Needle for Single Use, Infusion Set with Burette, Transfusion Set, Three Way Stopcock and Extension Tube, Syringe for Insulin, I.V. Flow Regulator for Single Use, Solution Administration Set for Infusion Pump, Urine Bag for Single Use, Multi-function Red Cap**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH2022001_2

Valid from: 2020-07-27
Valid until: 2023-05-31

Date, 2020-07-27

Digitally signed by Azarov Tatiana
Date: 2021.09.12 19:14:09 EEST
Reason: MoldSign Signature
Location: Moldova

Christoph Dicks
Head of Certification/Notified Body

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D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q6 056464 0019 Rev. 03

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Jiangsu Webest Medical Product Co., Ltd.
No.5 Yingchun Rd. Industrial park, 211700 Xuyi, JiangSu,
PEOPLE'S REPUBLIC OF CHINA

Jiangsu Webest Medical Product Co., Ltd.
No.18 Yingchun East Rd, Industrial Park, 211700 Xuyi, Jiangsu,
PEOPLE'S REPUBLIC OF CHINA

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D-ZM-11321-01-00

Product Service

Certificate

No. Q6 094558 0006 Rev. 02

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

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

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Production and Distribution of Infusion Sets with Needles, Intravenous Needles, Safety Syringe, Auto-disable Syringe, Urine Bags, Disposable Blood Transfusion Sets, Sterile Surgical Gloves, Sterile Examination Gloves, Feeding Tube, Stomach Tube, Suction Catheter, Nelaton Tube, Nasal Oxygen Cannula, Oxygen Mask, Rectal Tube, Vaginal Speculum, Disposable Blood Collection Needles, Gauze Pad, Gauze Roll, Syringe for Insulin, Disposable Blood Collection Tubes, Sterile Syringe for Single Use (with Needle), Sterile Syringe for Single Use (without Needle), Sterile Hypodermic Needle for Single Use**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH19100504
Valid from: 2019-04-11
Valid until: 2022-04-10

Date, 2019-04-11

Stefan Preiß

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TÜV SÜD
Product Service

Certificate

No. Q6 094558 0006 Rev. 02

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

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

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Production and Distribution of Infusion Sets with Needles, Intravenous Needles, Safety Syringe, Auto-disable Syringe, Urine Bags, Disposable Blood Transfusion Sets, Sterile Surgical Gloves, Sterile Examination Gloves, Feeding Tube, Stomach Tube, Suction Catheter, Nelaton Tube, Nasal Oxygen Cannula, Oxygen Mask, Rectal Tube, Vaginal Speculum, Disposable Blood Collection Needles, Gauze Pad, Gauze Roll, Syringe for Insulin, Disposable Blood Collection Tubes, Sterile Syringe for Single Use (with Needle), Sterile Syringe for Single Use (without Needle), Sterile Hypodermic Needle for Single Use**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH19100504
Valid from: 2019-04-11
Valid until: 2022-04-10

Date, 2019-04-11

Stefan Preiß

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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 056464 0018 Rev. 01

Manufacturer:

Jiangsu Webest Medical Product Co., Ltd.
No.5 Yingchun Rd. Industrial park
211700 Xuyi, JiangSu
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Sterile Infusion Sets for Single Use,
Sterile Syringes for Single Use,
Sterile Three-way Stopcocks for Single Use,
Sterile Heparin Caps for Single Use,
Sterile Dental Needles for Single Use,
Scalp Vein Set for Single Use,
I.V. Cannula for Single Use,
Hypodermic Needle for Single Use,
Infusion Set with Burette, Transfusion Set,
Three Way Stopcock and Extension Tube,
Syringe for Insulin,
I.V. Flow Regulator for Single Use,
Solution Administration Set for Infusion Pump

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.: SH1922017

Valid from: 2019-11-12
Valid until: 2023-07-08

Date, 2019-11-12

Christoph Dicks
Head of Certification/Notified Body

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

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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 056464 0018 Rev. 01

Facility(ies):

Jiangsu Webest Medical Product Co., Ltd.
No.5 Yingchun Rd. Industrial park, 211700 Xuyi, JiangSu,
PEOPLE'S REPUBLIC OF CHINA

Jiangsu Webest Medical Product Co., Ltd.
No.18 Yingchun East Rd, Industrial Park, 211700 Xuyi, Jiangsu,
PEOPLE'S REPUBLIC OF CHINA

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