



Certificate

No. Q5 094273 0011 Rev. 03

Holder of Certificate: **Shandong Weigao Group Medical Polymer Co., Ltd.**

No.18 Xingshan Road
Torch Hi-tech Science Park
264210 Weihai, Shandong Province
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Design and Development, Production, Sales, Distribution of Sterile 'Infusion Sets, Transfusion Sets, Hypodermic Syringes, Plastic Blood Bag, Intravenous Needles, Blood Collection Needles, Nasal Oxygen Cannula, High Pressure Angiographic Syringes, Retractable Auto-Disable Syringe, Prefillable Syringe Barrel (Without Needle), Prefillable Syringe Barrel (With Needle) ' for single use, Blood Collection Tubes, Sterile Precision Solution Filters for single use, Oral / Enteral Syringe for Single Use, Sterile Prefillable Syringe Stopper For Single Use, Prefillable Syringe Rod For Single Use, Sterile Micro-Filter Syringes for Single Use, Sterile Pressure Connector Tube For Single Use, Sterile COP Prefillable Syringe For Single Use, Infusion Sets with Precision Filters for Single Use, Light-resistant Infusion Sets for Single Use, Flow Rate-setting and Adjustable Infusion Sets with Precision Filters for Single Use, Sterile Dispensing Syringe for Single Use, Sterile Low Resistance Dispensing Syringe for Single Use, Sterile Irradiation-Resistance Dispensing Syringe with Needle for Single Use, Sterile Light-resistant Syringe with Needle for Single Use, Extension Tube for Single Use, Light-resistant Extension Tube for Single Use, Ultra-low Density Polyethylene Infusion Set for Single Use, Syringe Pump, Infusion Pump, Virus Sampling Kit for Single Use, Swab for Single Use.

Production of Blood Collection Devices.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 094273 0011 Rev. 03

Report No.: BJ21088402
Valid from: 2021-07-06
Valid until: 2023-09-30



Date, 2021-07-06

Christoph Dicks
Head of Certification/Notified Body

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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):

Shandong Weigao Group Medical Polymer Co., Ltd.
No.18 Xingshan Road, Torch Hi-tech Science Park, 264210
Weihai, Shandong Province, PEOPLE'S REPUBLIC OF CHINA

Management, Regulatory Affairs.

Shandong Weigao Group Medical Polymer Co., Ltd.
No.20 Xingshan Road, Torch Hi-tech Science Park, 264210
Weihai, Shandong Province, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production, Sales, Distribution of Sterile
'Infusion Sets, Transfusion Sets, Hypodermic Syringes,
Intravenous Needles, Blood Collection Needles, Nasal Oxygen
Cannula, High Pressure Angiographic Syringes, Retractable Auto-
Disable Syringe, Prefillable Syringe Barrel (Without Needle),
Prefillable Syringe Barrel (With Needle) ' for single use, Blood
Collection Tubes, Sterile Precision Solution Filters for single use,
Oral / Enteral Syringe for Single Use, Sterile Prefillable Syringe
Stopper For Single Use, Prefillable Syringe Rod For Single Use,
Sterile Micro-Filter Syringes for Single Use, Sterile Pressure
Connector Tube For Single Use, Sterile COP Prefillable Syringe
For Single Use, Infusion Sets with Precision Filters for Single Use,
Light-resistant Infusion Sets for Single Use, Flow Rate-setting and
Adjustable Infusion Sets with Precision Filters for Single Use,
Sterile Dispensing Syringe for Single Use, Sterile Low Resistance
Dispensing Syringe for Single Use, Sterile Irradiation-Resistance
Dispensing Syringe with Needle for Single Use, Sterile Light-
resistant Syringe with Needle for Single Use, Extension Tube for
Single Use, Light-resistant Extension Tube for Single Use, Ultra-
low Density Polyethylene Infusion Set for Single Use, Syringe
Pump, Infusion Pump, Virus Sampling Kit for Single Use, Swab for
Single Use.

Production of Blood Collection Devices.

Shandong Weigao Group Medical Polymer Co., Ltd.
No.10 Junshan Road, Torch Hi-tech Science Park, 264210 Weihai,
Shandong Province, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production, Sales, Distribution of Sterile
Plastic Blood Bag for Single Use.