



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

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in Class IIa, IIb or III)

**No. G1 094273 0003 Rev. 03**

**Manufacturer:**

**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

**Product Category(ies):**

Sterile 'Infusion Sets, Transfusion Sets, Hypodermic Syringes, Plastic Blood Bag, Intravenous Needles, Blood Collection Needles, High Pressure Angiographic Syringes, Retractable Auto-Disable Syringe, Oral / Enteral Syringe' for Single Use, Sterile Micro-Filter Syringes 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 Light-resistant Syringe with Needle for Single Use, Ultra-low Density Polyethylene Infusion Set for Single Use.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:**

BJ19884031

**Valid from:**

2020-02-18

**Valid until:**

2024-05-26

**Date,**

2020-02-18

Christoph Dicks  
Head of Certification/Notified Body



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## 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

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

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