

ZERTIFIKAT ♦ CERTIFICATE ♦ CERTIFICADO ♦ CERTIFIKAT ♦ 認證證書 ♦ CERTIFICATE ♦ CERTIFICATE



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.

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Date, 2020-02-18

Digitally signed by Șarco Alexandru
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Location: Moldova



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