Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-BS-244.10.08
www.zlg.de

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 003509 0002 Rev. 01

Manufacturer:

Zibo Qray International Co., Ltd.
No.77 Zhanghuan Road
255000 Zibo City, Shandong
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

ZOUSTECH S.L.
Pso. Castellana, 141 – Planta 19, 28046 Madrid, SPAIN

Product Category(ies):

Simple Oxygen Mask, Nebulizer With Mask, Nasal Oxygen Cannula, Sterile Hypodermic Syringes for Single Use, Sterile Hypodermic Needles for Single Use, Infusion Sets for Single Use, Feeding Tube, Stomach Tube, Suction Catheter, Nelaton Catheter, Sterile Heparin Caps for Single Use, IV. Cannula for Single Use, Three Way Stopcock and Extension Tube, Syringe for Insulin, I.V. Flow Regulator for Single Use, Transfusion Set, Infusion Set with Burette, Scalp Vein Set for Single Use, Sterile Safety Auto Disable Syringes for Single Use, Digital Blood Pressure Monitors (Digital Sphygmomanometers), Digital Thermometers, Infra-red Forehead Thermometers, Surgical Scalpel, Disposable Fistula Needles, Disposable Blood Lines, Disposable Endotracheal Tubes, Disposable Breathing Circuits, Disposable Insulin Pen Needles, Anesthesia Masks, Disposable Enteral Feeding Sets

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.: SH19130602

Valid from: 2019-08-02
Valid until: 2023-04-23

Date, 2019-08-02

Stefan Preiß
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
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Facility(ies):

Zibo Qray International Co., Ltd.
No.77 Zhanghuan Road, 255000 Zibo City, Shandong, PEOPLE'S REPUBLIC OF CHINA

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