ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 064660 0033 Rev. 02

Manufacturer:

Hospital & Homecare IMP. & EXP. Co., Ltd. Nanjing
Room 608-611
No. 5 Zhongtai International Plaza
No.311Middle of Jiangdong Road
Central Business District
210019 Nanjing
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

Product Category(ies):

Lap Sponges and X-ray Detectable Gauze Sponges, Sterile Surgical Gloves(Latex), Nelaton Catheters, Tracheal Tubes, Reinforced Endotracheal Tube, Oxygen Mask, Intubating Stylet, Laryngeal Mask Device, Non-Rebreath Mask, Aerosol Mask (Nebulizer mask), Sterile Heparin Caps for Single Use, I.V. Catheters, Sterile Three-way Stopcock for Single Use, Disposable Syringes with Needle, Disposable Insulin Syringes, Disposable Hypodermic Needles, Disposable Scalp Vein Sets, Disposable Infusion Sets, Disposable Blood Transfusion Sets, Disposable Surgical Blades, Blood Collection Needle, Blood Lancets for Single Use, Sterile Acupuncture Needles, Digital Blood Pressure Monitors, Electrocardiograph, Infusion Set with Burette, Multi-vent Masks, Disposable Skin Stapler, Endobronchial Tube, Wound Drainage System With and Without Trocar, Suction Catheters, Feeding Tubes, Suction Connecting Tube With and Without Yankauer, Nasal Oxygen Cannulas, Extension Set of Infusion Set, Stomach Tubes

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.: SH19287EXT01

Valid from: 2019-06-06
Valid until: 2024-05-26

Date, 2019-06-06

I. Preiß

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

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