ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Production Quality Assurance

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

No. G2 12 01 78540 002

Manufacturer:
Changzhou Standard Medical Devices Co., Ltd.
Tongjiang Road
Xinbei District
213022 Changzhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:
Wellkang Ltd t/a Wellkang Tech Consulting
Suite B, 29 Harley Street
London
W1G 9QR
UNITED KINGDOM

Product Category(ies):
Endotracheal Tubes,Suction Catheter,
Tracheostomy Tubes, Oxygen Masks,
Silicone Foley Catheters,
Nelaton Catheters,
Nasal Oxygen Cannulaes,
Feeding Tubes, Latex Surgical Gloves,
Sterile Gauze Swab with X-ray,
Sterile Lap Sponge with X-ray,
Disposable Intravenous Needles,
Sterile Syringes for Single Use,
Hypodermic Needle for Single Use,
Sterile Infusion Sets for Single Use,
Transfusion Set, I.V. Cannula for Single Use,
Sterile Dental Needles for Single Use,
Latex Foley Catheter,Stomach Tube,
Umbilical Cord Clamp

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.: SH1170201
Valid from: 2012-03-07
Valid until: 2017-03-06

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Date, 2012-03-13

Hans-Heiner Junker

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

TÜV®

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