



Product Service

CERTIFICATE

No. Q1N 06 06 59388 001

Holder of Certificate: Ningbo China Tianyi Medical Appliance Co., Ltd.

No. 788, Qianhu North Road
Tourism Resort, Dongqian Lake
315121 Ningbo
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Ningbo China Tianyi Medical Appliance Co., Ltd.
No. 788, Qianhu North Road, Tourism Resort, Dongqian Lake,
315121 Ningbo, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Design and Development, Production and Distribution of Sterile Hypodermic Syringe, Transfusion Sets, Intravenous Needles, Burette-type Infusion Sets, Plasmapheresis Centrifuge Apparatus: Centrifuge Bowl, Plasmapheresis Centrifuge Apparatus: Plasma Tubing, Extracorporeal Blood Circuit for Haemodialysers, Haemodiafilters and Haemofilters, Infusion Sets, Single Use Bloodtaking Set for Blood Processing Equipment (Arterial-Venous Fistula Needle Set)

Applied Standard(s):

ISO 13485:2003
Medical Devices - Quality Management Systems - Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 70198646801

Valid until: 2009-06-30

Date, 2006-07-11

Reiner Krumme



Page 1 of 1

TÜV Product Service GmbH
TÜV SÜD Gruppe · Zertifizierstelle
Ridlerstr. 65 · 80339 München
Germany



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-999.98.12-46