



Product Service

EC-CERTIFICATE

Production Quality Assurance System

(Annex V of the Directive 93/42/EEC on Medical Devices)

No. G2 06 06 59388 002

Manufacturer: Ningbo China Tianyi Medical Appliance Co., Ltd.

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

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)

Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):

Infusion Sets for Single Use (Gravity Feed),
Extra-corporeal Blood Circuit for Haemodialysers,
Haemodiafilters and Haemofilters,
Single Use Blood-taking Set for Blood Processing
Equipment (Arterial-Venous Fistula Needle Set)

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 products / product categories according to Annex V, section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class IIb and III products an additional Annex III - certificate is mandatory. See also notes overleaf.

Report No.: 70198646801

Valid until: 2011-07-10



Date, 2006-07-11

Reiner Krumme

TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

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