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

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 16 05 44803 027

Manufacturer:

Jiangxi Hongda Medical Equipment Group Ltd.
39 South Shengli RD, Jinxian County
331700 Nanchang, Jiangxi Province
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

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

Product Category(ies):

Infusion and Transfusion Sets for Single Use,
Syringes and Needles for Single Use,
scalp vein sets for single use,
Blood Collection Sets for Single Use,
Sterile Single-use Dental Injection Needles,
Sterile Autodisable Syringe for single use,
Disposable Suction Catheter for use in Respiratory Tract and Disposable Stomach Catheter,
Single-use Sterile rubber surgical gloves,
Disposable sterile needle retractable safety syringe,
IV Cannula for single use, Foley Catheter for single use,
Endotracheal tube for single use,
A.V. fistula needle sets for single use,
Burette-type infusion sets for single use,
Heparin cap for single use,
Sterile insulin syringe for single use,
Blood Tubing Set for Hemodialysis.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: BJ1689304 / BJ16893041

Valid from: 2016-07-01
Valid until: 2017-12-03

Date, 2016-07-01

Stefan Preiß

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

TÜV®

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

Product Service

EC Certificate
Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 16 05 44803 027

Facility(ies):

Jiangxi Hongda Medical Equipment Group Ltd.
39 South Shengli RD, Jinxian County, 331700 Nanchang, Jiangxi Province, PEOPLE'S REPUBLIC OF CHINA

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®