



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 047330 0054 Rev. 00

Manufacturer:

FIRSTAR HEALTHCARE

COMPANY LIMITED (GUANGZHOU)

Rm.901

Building No.2, Headquarters Center Tian'an High-tech Ecological Park

Panyu

511400 Guangzhou

PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

FIRSTAR HEALTHCARE COMPANY LIMITED (GUANGZHOU) Rm.901, Building No.2, Headquarters Center, Tian'an High-tech

Ecological Park, Panyu, 511400 Guangzhou, PEOPLE'S

REPUBLIC OF CHINA

FIRSTAR MEDICAL INDUSTRIAL LTD.

No.4-5, 2nd Industrial District, Dongshen Cun Dongchong Town, Nansha, 511475 Guangzhou, PEOPLE'S REPUBLIC OF CHINA

Product

Category(ies):

Infusion Sets, Transfusion Sets, Sterile HypodermicNeedles,

Scalp Vein Sets for Single Use, Foley Catheters, Tracheal Tubes, Surgical Blades, Blood Lancets,

Nelaton Catheters, Digital Thermometers,

Tracheostomy Tubes, Stopcocks, Blood Collecting Needles, Oxygen Masks, Connecting Tube With Yankauer Handle,

CPR Masks, Dental Needles, Extension Tubes,

Nasal Oxygen Cannulae, Face Masks With Air Cushion,

Instant Cold Pack, All Silicone Foley Catheter,

Wound Drainage System, Intra-red Ear Thermometers,

First Aid Kit, Resuscitator,

Sterile Single Use Cleansing Tube, Foam Dressing,

Sterile Syringes with Needle for Single Use,

Sterile Auto-disable Syringes with Needle

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.

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Stefan Preiß

I. Pumil

