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

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 16 08 95925 003

Manufacturer:

Shanghai Medic Industry Co., Ltd.
Room 2801 No.5 Lane 689 Li Quan Road
200333 Shanghai
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

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

Product Category(ies):

Infusion Set with Burette for Single Use,
Syringe for Insulin for Single Use,
Transfusion Set for Single Use,
Three Way Stopcock and Extension Tube for Single Use, I.V. Flow Regulator for Single Use,
Sterile Infusion Sets for Single Use,
Sterile Syringes for Single Use,
Scalp Vein Set for Single Use,
I.V. Cannula for Single Use,
Hypodermic Needle for Single Use,
Sterile Heparin Caps for Single Use,
Sterile Dental Needles for Single Use

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.: SH16107501

Valid from: 2016-12-13
Valid until: 2021-12-12

Date, 2016-12-12

Stefan Preiß

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

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Facility(ies):

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

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