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

TÜV SÜD 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 17 08 81494 013

Manufacturer:

Sino Medical-Device Technology Co., Ltd.
6th Floor, Building 15
No. 1008, Songbai Road
Nanshan District
518055 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

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

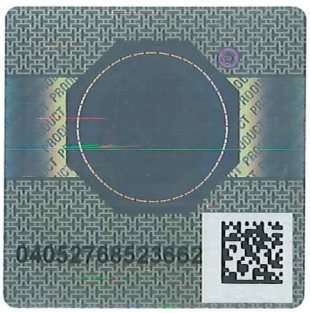
Product Category(ies):

High-pressure Injector, Syringe Pump, Mammography, Infusion Pump, Enteral Nutrition Pump, Infusion Warmer, Infusion Monitoring System, Syringe Pump Station

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.: GZ1707901

Valid from: 2018-03-23
Valid until: 2022-08-27



Date, 2018-03-23

Stefan Preiß

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

Digitally signed by Maxim Victor
Date: 2021.07.06 09:24:18 EEST
Reason: MoldSign Signature
Location: Moldova

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Facility(ies):

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518055 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

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