



## 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 04 81494 011

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** 

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.:

GZ17079EXT01

Valid from:

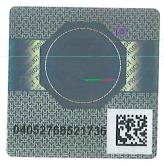
2017-10-16

Valid until:

2022-10-15

Date, 2017-10-16

Stefan Preiß



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

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518055 Shenzhen, PEOPLE'S REPUBLIC OF CHINA