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Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
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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 104715 0002 Rev. 01**

**Manufacturer:**

**Jiangsu Sinowise Technology  
Co., Ltd**

198th ZhaoXia Road, Nantong  
High-Tech Zone, Jiangsu Province  
PEOPLE'S REPUBLIC OF CHINA

**Product Category(ies): Infusion Pump, Syringe Pump  
Infusion Warmer, Patient Warming Machine**

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G11047150002Rev.01](http://www.tuvsud.com/ps-cert?q=cert:G11047150002Rev.01)

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**Date,** 2021-04-23

Christoph Dicks  
Head of Certification/Notified Body