



EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 093011 0007 Rev. 01

Manufacturer

**Ningbo Foyomed Medical
Instruments Co., Ltd.**

Room 805-806

No. 299 of Jiangnan Yipin Garden

Hi-Tech Zone

315040 Ningbo

PEOPLE'S REPUBLIC OF CHINA

Product

Category(ies):

Sterile Non-active Medical Devices

(for detailed information see following pages)

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.:

SH19994EXT01

Valid from:

2019-11-27

Valid until:

2024-05-26

Date,

2019-11-27

Christoph Dicks

Head of Certification/Notified Body

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Facility(ies):

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Room 805-806, No. 299 of Jiangnan Yipin Garden,
Hi-Tech Zone, 315040 Ningbo, PEOPLE'S
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