



EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class IIa Devices)

No. G20 094558 0009 Rev. 00

Manufacturer:

**Jiangyin Fanmei Medical
Device Co., Ltd.**

No.19 Yishan Rd, Lingang Street
214400 Jiangyin
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000025931

Authorized Representative:

MedPath GmbH
Mies-van-der-Rohe-Strasse 8, 80807 Munich, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. The Notified Body confirms that the class IIa devices in question conform to the technical documentation and meet the requirements of this Regulation which apply to them. Details on device categories covered by the quality management system are described on the following page(s).

The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex XI Part A of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality assurance system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.

For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G20 094558 0009 Rev. 00

Report No.: SH23100501

Valid from: 2024-09-24

Valid until: 2029-09-23

Issue date: 2024-09-24

Christoph Dicks
Head of Certification/Notified
Body



EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
 (Class IIa Devices)

No. G20 094558 0009 Rev. 00

Classification: Class IIa
Device Group: A0101010102 - HYPODERMIC SYRINGE NEEDLES, W/O SAFETY SYSTEMS

Classification: Class IIa
Device Group: A02010499 - SYRINGES FOR INJECTOR, SINGLE-USE - OTHER

Classification: Class IIa
Device Group: A02010601 - INSULIN SYRINGES WITH FIXED NEEDLE, SINGLE-USE

The validity of this certificate depends on conditions and/or is limited to the following: NA

Revision History:

Rev.	Dated	Report	Description
00	2024-09-24	SH23100501	Initial issuance