CERTIFICADO ◆ 인증서 ◆ CERTIFICATO ◆ 認証書 ◆ CERTIFICATE ◆ 认证证书 ◆ ZERTIFIKAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

EU Production Quality Assurance Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A

Certificate No. G26 103129 0005 Rev. 00

Manufacturer:

Shandong Chengwu Medical Products Factory
Southern end of Quancheng Road
Chengwu County
274200 Heze City, Shandong Province
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000003370

Authorized Representative:

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

The quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex XI Part A with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.
The certified quality management system is subject to periodical surveillance.

If class I devices in sterile conditions, with measuring function, or reusable surgical instruments are covered by this certificate, the audit was limited to the respective aspects relating to
- establishing, securing, and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

If class IIa devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The devices conform to the technical documentation. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class IIb or class III (excluding custom-made implantable devices) devices are covered by this certificate, the quality management system ensures that devices conform to the type that has undergone a type examination. An EU Type-Examination Certificate in accordance with Annex X is required before placing them on the market.

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:G26 103129 0005 Rev. 00

Report No.: BJ24076602
Valid from: 2026-08-14
Valid until: 2031-08-13

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2026-08-14

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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EU Production Quality Assurance Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A

Certificate No. G26 103129 0005 Rev. 00

Classification:	Class IIa
Device Group:	MDN 1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis
The validity of this certificate depends on conditions and/or is limited to the following:	- none -

Revision History:

Rev.	Dated	Report	Description
00	2026-08-14	BJ24076602	Initial issuance

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