ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

Product Service

EU Production Quality Assurance Certificate

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

Certificate No. G26 119776 0004 Rev. 00

Manufacturer:

Hubei MeterOmega Technology LTD
1F&2F, Building 3
Biomedical Industrial Park
Jianqiu 5th Road
Duodao District
448000 Jingmen City, Hubei Province
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000016732

Authorized Representative:

Humiss Beratung GmbH
Gneisenaustraße 8, 40477 Düsseldorf, 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 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 119776 0004 Rev. 00

Report No.: SH23208601
Valid from: 2025-06-23
Valid until: 2030-06-22

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-06-23

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

Certificate No. G26 119776 0004 Rev. 00

Classification:	Class I
Device Group:	M040599 - HAEMOSTATIC DRESSINGS - OTHER
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class IIa
Device Group:	MDN 1201 - Non-active non-implantable devices for anaesthesia, emergency and intensive care
Intended Purpose:	Arterial Blood Gas Sampler is intended for the collection of arterial whole blood specimens for the purpose of blood-gas analysis.
The validity of this certificate depends on conditions and/or is limited to the following:	NA

Rev.	Dated	Report	Description
00	2025-06-23	SH23208601	Initial issuance

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