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-IVDR-099

Product Service

EU Quality Management System Certificate

Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapter I

Certificate No. V13 126886 0002 Rev. 00

Manufacturer:

GenSure Biotech Inc.
5F, No. 5, Lane 396, Luzhouhuan Rd.
Minhang District
201114 Shanghai
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000028354

Authorized Representative:

Riomavix S. L.
Calle de Almansa 55, 1D, 28039 Madrid, SPAIN

The quality management system has been evaluated in accordance with Regulation (EU) 2017/746, Annex IX Chapter I 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 A devices in sterile conditions are covered by this certificate, the audit was limited to the aspects relating to establishing, securing, and maintaining sterile conditions.
If class B or C excluding self-/near-patient-testing, or class C companion diagnostics 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 periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class D devices, class B or C self-/near-patient testing, or class C companion diagnostics devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II 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:V13 126886 0002 Rev. 00

Report No.: SH24235605
Valid from: 2025-07-16
Valid until: 2030-07-15

Marta Carnielli
Head of Certification IVD

Issue date: 2025-07-16

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TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Classification:	Class C
Device Group:	IVR 0503 - Infectious agent detection: Presence of, or exposure to an infectious agent
Device Properties:	IVS 1002 - Devices intended to be used for self-testing
Intended Purpose:	See product certificate
Classification:	Class B
Device Group:	IVR 0607 - Physiological status and therapeutic measures: Pregnancy or fertility testing
Device Properties:	IVS 1002 - Devices intended to be used for self-testing
Intended Purpose:	See product certificate
The validity of this certificate depends on conditions and/or is limited to the following:	-None-

Rev.	Dated	Report	Description
00	2025-07-16	SH24235605	Initial issuance

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