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 Technical Documentation Assessment Certificate (IVDR)

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

No. V76 126886 0005 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 technical documentation has been evaluated in accordance with Regulation (EU) 2017/746, Annex IX Chapter II with a positive result.Details on devices covered by the technical documentation 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.

If class B or C self-/near-patient testing are covered by this certificate, the assessment was conducted according to section 4 and 5.1. An EU Quality Management System Certificate in accordance with Annex IX Chapter I is required before placing them on the market.
If class C companion diagnostics devices are covered by this certificate, the assessment was conducted according to section 4 and 5.2. An EU Quality Management System Certificate in accordance with Annex IX Chapter I is required before placing them on the market.
If class D devices are covered by this certificate, verification of batches of manufactured devices according to Annex IX Sections 4.12 and 4.13 is applicable. An EU Quality Management System Certificate in accordance with Annex IX Chapter I 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:V76 126886 0005 Rev. 00

Report No.: SH24235601
Valid from: 2025-07-11
Valid until: 2030-07-10

Issue date: 2025-07-11

Marta Carnielli
Head of Certification IVD

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Classification: Class C self-testing

Basic UDI-DI: 697683823P201900F9

Intended Purpose: The Strep A Rapid Test is a lateral flow immunoassay for the rapid, qualitative detection of Group A streptococcal (GAS, Strep A) antigen from throat swabs of individuals who suspected of Strep A infection. The test is used as an aid in the diagnosis of Strep A infection. It is a non-automated device intended for professional laboratory use and self-testing.
Children under 15 years old should be sampled and tested by adults.

Device Group: IVR 0503 - Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents

Device(s): Strep A Rapid Test

GenSure Strep A Rapid Test:
P2019C01, P2019C02, P2019C05, P2019C10, P2019C20

EuroGen Strep A Rapid Test:
Y2019C01, Y2019C02, Y2019C05, Y2019C10, Y2019C20

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

Revision History:

Rev.	Dated	Report	Description
00	2025-07-11	SH24235601	Initial issuance

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