Declaration of Conformity

Manufacturer	GenSure Biotech Inc. Add.: 5F, No. 5, Lane 396, Luzhouhuan Rd., Minhang District, 201114 Shanghai, China SRN: CN-MF-000028354
European Representative	Riomavix S.L. Add.: Calle de Almansa 55, 1D, Madrid 28039 Spain SRN: ES-AR-000001202
Product	Common name: Strep A Rapid Test Trade name: GenSure Strep A Rapid Test, or EuroGen Strep A Rapid Test REF: P2019C01, P2019C02, P2019C05, P2019C10, P2019C20 (for GenSure brand); Y2019C01, Y2019C02, Y2019C05, Y2019C10, Y2019C20 (for EuroGen brand) Basic UDI-DI: 697683823P201900F9 EMDN Code: W0105090103 Intended Use: 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.
Notified body	Name: TUV SUD Product Service GmbH Identification: 0123

Conformity Assessment Route	Annex IX of In Vitro Diagnostic Regulation (EU) 2017/746
Classification of Medical Device	Class C according to Annex VIII, Rule 4 (a)

This EU declaration of conformity is issued under the sole responsibility of GenSure Biotech Inc. We herewith declare that the above mentioned product is in conformity with the REGULATION (EU)2017/746, and meet the provisions of the following EC Council Regulations and Standards.

Standard Applied	REGULATION (EU)2017/746 EN ISO13485: 2016 EN ISO 15223-1: 2021 EN ISO 20417: 2021 EN ISO 14971: 2019 ISO 18113-1: 2022

ISO 18113-2: 2022

ISO 18113-4: 2022

EN ISO 20417: 2021

EN 13612: 2002

EN ISO 23640: 2015

EN 62366-1: 2015

IEC/TR 62366-2: 2016

ISO 20916: 2019

CLSI EP17-A2

CLSI EP12-A3

CLSI EP05-A3

CLSI EP07-A3

CLSI EP25-A2

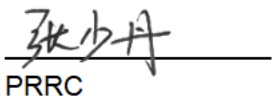
CLSI EP24-A2

MDCG 2022-2

Certificate Identification: No. V76 126886 0005 Rev. 00
Expiration date: 2030-07-10

Place/ Date of issue Shanghai, 2025-07-11

Zhang Shaodan

Signature: 

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