EU DECLARATION OF CONFORMITY

According to Regulation (EU) 2017/746 on in vitro diagnostic Medical Devices

Manufacturer name:	Zhejiang Greylynx Biotech Co., Ltd.
Manufacturer Address:	Floor 3&4, Building 4, No. 17 Jianxing Road, Taozhu Street Zhuji, 311800, Zhejiang, P.R. China
Brand:	GREYLYNX
SRN:	CN-MF-000032462
European Representative:	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, the Hague, Netherlands. Tel: +31644168999 E-mail: peter@lotusnl.com
SRN:	NL-AR-000000121
Trade mark:	Greylynx
Product or trade name:	Strep A Rapid Test
Intended Use:	The Greylynx Strep A Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection patient of Strep A antigen in human throat swab samples and it's not automated. This product is suitable for specific patient self-testing over 16 years of age. It is suggested that individual age from 3-16 should be tested by a parent or legal guardian. It is an in-vitro diagnostic reagent intended for use as an aid in the diagnosis of strep A infection in patients with typical symptoms, such as fever, pharyngitis, etc.

<table>
<tr><td>Product List:</td><td>
<table>
<tr><th>Product name</th><th>Components</th><th>Model</th><th>REF No.</th></tr>
<tr><td>Strep A Rapid Test</td><td>1 test device / 1 Disposable Swab/ 1 Reagent 1/ 1 Reagent 2 / 1 Test tube / 1 Tube tip/ 1 Tube stand/ 1 Package Insert</td><td>GISTA-702H</td><td>GISTA-702H(1T/kit)</td></tr>
<tr><td>Strep A Rapid Test</td><td>2 test devices / 2 Disposable Swabs/ 1 Reagent 1/ 1 Reagent 2 / 2 Test tubes / 2 Tube tips/ 1 Tube stand/ 1 Package Insert</td><td>GISTA-702H</td><td>GISTA-702H(2T/kit)</td></tr>
<tr><td>Strep A Rapid Test</td><td>5 test devices / 5 Disposable Swabs/ 1 Reagent 1/ 1 Reagent 2 / 5 Test tubes / 5 Tube tips/ 1 Tube stand/ 1 Package Insert</td><td>GISTA-702H</td><td>GISTA-702H(5T/kit)</td></tr>
<tr><td>Strep A Rapid Test</td><td>25 test devices / 25 Disposable Swabs/ 1 Reagent 1/ 1 Reagent 2 / 25 Test tubes / 25 Tube tips/ 1 Tube stand/ 1 Package Insert</td><td>GISTA-702H</td><td>GISTA-702H(25T/kit)</td></tr>
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</td></tr>
<tr><td>Basic UDI-DI:</td><td>697620276GISTA000014E</td></tr>
<tr><td>Classification acc. to IVDR Ax. VIII:</td><td>The Strep A Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of Strep A antigen in human throat swab samples, it is only for self-testing, not for near-patient testing. Based on Classification Rule 4(a), Annex VIII, classification rules, the device is considered to be a Class C medical device.</td></tr>
<tr><td>Conformity assessment procedure:</td><td>Annex IX chapter I, chapter II, Sections 4 and 5.1 and Chapter III, Regulation (EU) 2017/746 (IVDR)</td></tr>
<tr><td>EU Technical Documentation Assessment Certificate (IVDR):</td><td>IX 2566030-1</td></tr>
<tr><td>EU Quality Management System Certificate (IVDR):</td><td>HX 2566030-1</td></tr>
<tr><td>Name of the Notified Body:</td><td>TÜV Rheinland LGA Products GmbH</td></tr>
</table>

ID of the Notified Body:	0197
Standards Applied:	Please refer to Annex 1 - Standards Applied List.
We, the manufacturer, herewith declare under our sole responsibility that the mentioned products meet the provisions of the Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR) and related standards. All supporting documentations are retained under the premises of the manufacturer.	
Signature:	
Name and Position:	Julie Zhou, General Manager
Place and Date of Issue:	In Zhuji on March 14, 2025

Annex 1 - Standards Applied List

Applicable Standard	Content
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 13485:2016/AC:2018	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
ISO/TR 24971:2020	Medical devices — Guidance on the application of ISO 14971(ISO/TR 24971:2020)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 18113-1:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements (ISO 18113-1:2022)
EN ISO 18113-4:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: In vitro diagnostic reagents for self-testing (ISO 18113-4:2022)
EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices EN 13612:2002/AC:2002
EN ISO 20916:2024	In vitro diagnostic medical devices-clinical performance studies using specimens from human subjects-Good study practice (EN ISO 20916:2019)
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)
EN 62366-1:2015/A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2020)
MEDDEV 2.12/2 rev2	Post market clinical follow-up studies
MEDDEV. 2.7.1 Rev.4	Performance evaluation: Guide for manufacturers and Notified Bodies (June 2016)
CLSI EP07-A3	Interference Testing in Clinical Chemistry- Third Edition
CLSI EP12-A3	Evaluation of Qualitative, Binary Output Examination Performance - Third Edition

CLSI EP17-A2	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures, 2nd Edition
CLSI EP25-A2	Evaluation of Stability of In Vitro Medical Laboratory Test Reagents, 2nd Edition
GHTF/SG5/N7:2012	Clinical Evidence for IVD medical devices–Scientific Validity Determination and Performance Evaluation
MDCG 2022-2	Guidance on general principles of clinical evidence for In Vitro Diagnostic medical devices (IVDs)
REGULATION (EU) 2017/746	REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices