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, Section 4, 5.1
(Class C and B Devices for self-testing and near patient testing)

No. V74 095123 0010 Rev. 01

Manufacturer:

Hangzhou AllTest Biotech Co., Ltd.
550#, Yinhai Street
Hangzhou Economic and Technological Development Area
310018 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000010710

Authorized Representative:

MedNet EC-REP GmbH
Borkstraße 10, 48163 Münster, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the Technical Documentation are described on the following page(s).
The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX, Chapter II, Section 4, 5.1 of this regulation with a positive result.
In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX Chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V74 095123 0010 Rev. 01

Report No.: SH23106403_CN_PRD

Preceding Certificate No.: V74 095123 0010 Rev. 00

Valid from: 2023-11-29
Valid until: 2027-07-06

Date of Initial Issuance: 2022-07-07

Marta Carnielli
Head of Certification IVD

Issue date: 2023-11-29

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TÜV SÜD Product Service

EU Technical Documentation Assessment Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX, Chapter II, Section 4, 5.1
(Class C and B Devices for self-testing and near patient testing)

No. V74 095123 0010 Rev. 01

Classification:	Class B
Device Group:	W010509 - INFECTIOUS IMMUNOLOGY - RAPID TESTS & POINT OF CARE
Basic UDI-DI:	6970277510000AXB
Intended Purpose:	The Strep A Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of Strep A antigens in throat swab specimens. The Strep A Rapid Test is for near-patient and laboratory professional in vitro diagnostic use only and is intended to be used as an aid in the diagnosis of Group A Streptococcal infections. The test provides preliminary test results, negative results will not preclude Strep A infection and they can't be used as the sole basis for treatment or other management decision. Not for Self-testing use.
Device(s):	Strep A Rapid Test, REF no. IST-N501 and IST-N502 IST-N501J-25, IST-N501B-25, IST-N502J-20, IST-N502B-20, IST-N501 (GIMA 24521), IST-N502 (GIMA 24520)
The validity of this certificate depends on conditions and/or is limited to the following:	- none -

Revision History:

Rev.	Dated	Report	Description
00	2022-07-07	SH211064IVDR01	-
01	2023-11-29	SH23106403_CN_PRD	Supplemented: Device(s)/group of device(s) added

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Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX Chapters I and III (Class D Devices, Class C and B Devices for self-/near-patient testing, Class C Devices Companion Diagnostics)

No. V10 095123 0011 Rev. 00

Manufacturer:

Hangzhou AllTest Biotech Co., Ltd.
550#, Yinhai Street
Hangzhou Economic and Technological Development Area
310018 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer: CN-MF-000010710

Authorized Representative:

MedNet EC-REP GmbH
Borkstrasse 10, 48163 Muenster, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s). The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Technical Documentation Assessment Certificate pursuant to the applicable Section(s) of Annex IX Chapter II is necessary in addition to this EU Quality Management System Certificate.
For details and certificate validity see:www.tuvsud.com/ps-cert?q=cert:V10 095123 0011 Rev. 00

Report No.: SH211064IVDR02

Valid from: 2022-07-12

Valid until: 2027-07-11

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-07-12

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Product Service

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Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX Chapters I and III (Class D Devices, Class C and B Devices for self-/near-patient testing, Class C Devices Companion Diagnostics)

No. V10 095123 0011 Rev. 00

Classification:	B
Device Group:	W010509 - INFECTIOUS IMMUNOLOGY - RAPID TESTS & POINT OF CARE
Intended Purpose:	IVR 0503 - Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents
The validity of this certificate depends on conditions and/or is limited to the following:	- none -

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