

EU Declaration of Conformity

Manufacturer: HANGZHOU ALLTEST BIOTECH CO., LTD.

Address: #550, Yinhai Street, Hangzhou Economic & Technological Development Area, Hangzhou
-310018, P.R. China

SRN: CN-MF-000010710

Product Name:	Strep A Rapid Test		
REF:	IST-N501/IST-N502	Classification According to IVDR Annex VIII Rule 6 :	Class B
EMDN Code:	W0105090103		
Basic UDI-DI:	6970277510000AXB	Conformity Assessment Procedure:	IVDR Annex IX Chapters I, III and Section 4, 5.1 of Chapter II
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.		

We, HANGZHOU ALLTEST BIOTECH CO., LTD, herewith declare that the EU declaration of conformity is issued under the sole responsibility of above manufacturer. The above mentioned product is in conformity with REGULATION (EU) 2017/746 and following Standards: EN ISO 13485:2016, EN ISO 14971:2019, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, ISO 20916:2019, EN ISO 23640:2015, EN 13641:2002, EN ISO 15223-1:2021, EN 62366-1:2015.

Notified Body:

Address:

Notified Body No.:

EU Quality Management System Certificate:

Expire date of EU QMS Certificate:

EU Technical Documentation Assessment Certificate:

Expire date of EU TDA Certificate:

Start of CE Marking:

TÜV SÜD Product Service GmbH

Ridlerstrasse 65, 80339 Munich, Germany

0123

V10 095123 0011 Rev. 00

2027-07-11

V74 095123 0010 Rev. 00

2027-07-06

2022-07-12

European Representative:

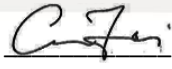
Address:

SRN:

MEDNET EC-REP GmbH

Borkstrasse 10, 48163 Muenster, Germany

DE-AR-000000002

Signature: 

Name and Position: Gao Fei, General Manager

Place, Date of Issue: in Hangzhou on 2023-02-13

