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: TÜV SÜD Product Service GmbH
Address: Ridlerstrasse 65, 80339 Munich, Germany
Notified Body No.: 0123
EU Quality Management System Certificate: V10 095123 0011 Rev. 00
Expire date of EU QMS Certificate: 2027-07-11
EU Technical Documentation Assessment Certificate: V74 095123 0010 Rev. 01
Expire date of EU TDA Certificate: 2027-07-06
Start of CE Marking: 2022-07-12

European Representative: MEDNET EC-REP GmbH
Address: Borkstrasse 10, 48163 Muenster, Germany
SRN: DE-AR-000000002

Signature:
Name and Position: Gao Fei, General Manager

Place, Date of Issue: in Hangzhou on 2023-12-04