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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

Device Trade Name:	**Strep A Rapid Test**		
REF:	ISTB-N502H-01/ISTB-N502H-05/ISTB-N502H-07/ISTB-N502H-10/ISTB-N502H-20		
EMDN Code:	W0105090103	**Classification According to IVDR Annex VIII Rule 4a :**	Class C
Basic UDI-DI:	6970277510014PYS	**Conformity Assessment Procedure:**	IVDR Annex IX Chapters I, III and Section 4, 5.1 of Chapter II
Intended Purpose:	The test is a rapid chromatographic immunoassay for the qualitative detection of Strep A antigens from self-collected throat swab specimens to aid in the diagnosis of Group A Streptococcal infection. The test is not automated. For self-testing use. For in vitro diagnostic use only.		

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, ISO 18113-1:2022, ISO 18113-4:2022, ISO 20916:2019, EN ISO 23640:2015, EN 13641:2002, EN ISO 15223-1:2021, EN 62366-1:2015, EN 13532:2002

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
Expire date of EU QMS Certificate: 2027-07-11
EU Technical Documentation Assessment Certificate: V76 095123 0019
Expire date of EU TDA Certificate: 2030-07-08
Start of CE Marking: 2025-07-09

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 2025-07-09

HANGZHOU ALLTEST BIOTECH CO., LTD. 33011800841