CE

DECLARATION OF CONFORMITY

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer:	Hangzhou Tongzhou Biotechnology Co., Ltd.
Address:	No. 1 Ninghong Road, Donghu Street, Linping District, Hangzhou, Zhejiang 311199, P.R.China.
EC Representative:	CMC Medical Devices & Drugs S.L.
Address:	C/Horacio Lengo № 18 CP 29006, Málaga-Spain
Product Name:	Streptococcus pneumoniae Antigen Rapid Test
Classification：	Other
Conformity Assessment Procedure:	Annex III of In Vitro Diagnostic Directive (98/79/EC)
CE N/REF:	PS/RPS/215/2022

We herewith declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN ISO13485:2016, EN ISO14971:2019, EN 13975:2003, EN ISO 18113-1:2022, EN ISO 18113-2:2022, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO23640:2015, EN 13641:2002, EN ISO 15223-1:2021

Signature: Steve Shao

Hangzhou Tongzhou Biotechnology Co., Ltd.

Name / Position:Steve Shao / General Manager

Place, Date of First Issue of DOC: in Hangzhou on 25/05/2022

Date of Issue of DOC on 15/09/2026