CE

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Manufacturer: Zhejiang Anji Saianfu Biotech Co.,Ltd
2nd Floor,No 3 Factory, No 489 WenYun Road,TangPu Industrial Park,Dipu Subdistrict, Anji county,313303 HuZhou City, ZheJiang Province, China

No.	Product Name	Model
1	COVID-19 AG & INFLUENZA A/B COMBO RAPID TEST	Cassette
2	COVID-19 /Flu A&B /RSV Ag Combo Rapid Test	Cassette
3	COVID-19 /Flu A&B /RSV /ADENO Ag Combo Rapid Test	Cassette
4	COVID-19 /Flu A&B /RSV /ADENO/M.P Ag Combo Rapid Test	Cassette
5	COVID-19 /Flu A&B /RSV /ADENO/M.P/HPIV Ag Combo Rapid Test	

Conformity assessment route: Annex III (EC DECLARATION OF CONFORMITY)
Harmonized standards:
EN ISO 13485:2016
EN 15223-1:2021
EN ISO 14971:2019
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN 980:2016
EN 13640:2002
EN 13612:2002

We, the Manufacturer, herewith declare with sole responsibility that our products mentioned
above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint **MedUnion S.L located at Carrer de Tapioles, 33, 2-1, 08004, Barcelona, Spain** to act as our European Authorised Representative as defined in the aforementioned Directive.

Signed on 1 /(Day)/ 3 /(Month) of 2022 /(Year).
Place Anji, Zhejiang, China
Represented by

Signature:
Name of authorized signatory: Wang Qin
Position held in the company: General Manager
Seal/Stamp: