

EC Declaration of Conformity

Manufacturer:

Name: Multibrands Trading (Suzhou) Co., Ltd.

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Whose Authorized Representative:

Name: Lotus NL B.V.

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We, Multibrands Trading (Suzhou) Co., Ltd. (Manufacturer), here declare that the below mentioned medical device meets the provisions of Directive 98/79/EC which apply to them. The declaration of conformity is exclusively under the responsibility of Multibrands Trading (Suzhou) Co., Ltd. (Manufacturer).

Product Name	SARS-CoV-2/FluA/FluB Antigen Combo Rapid Test Kit	Packaging Specification	1 Test/Box 24 Tests/Box
Intended Use	Both COVID-19 and influenza A/B viruses (Flu A/B) can cause acute respiratory infections, and people are generally susceptible. These three viruses are highly contagious, spread quickly, have a short incubation period, and have a high incidence. The main symptoms are fever, dry cough, fatigue, etc. Therefore, the detection of COVID-19, Flu A/B has relatively Great clinical findings.		
Classification	Others		

Conformity Assessment Route: IVDD 98/79/EC Annex III (excluding Annex III.6).

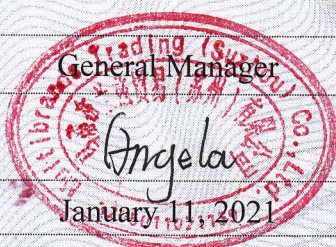
Applicable Standards:

EN ISO 13485:2016
ISO 14971:2019
EN ISO 18113-1:2011

EN ISO 18113-2:2011
EN 13641:2002
ISO 15223-1:2016

EN 13612:2002
ISO 23640:2015
EN 62366-1:2015



Name Of Authorized Signatory	
Position Held In The Company	
Signature	
Date	
Place	
Seal (Manufacturer)	Suzhou, China.