

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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E-mail: peter@lotusnl.com

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 Antigen Saliva Test Kit (Colloidal Gold)	Code&package Specification	PDSTKA-U 24tests/inner box 288tests/outer carton
Intended Use	The SARS-CoV-2 Antigen Saliva Test Kit (Colloidal Gold) is a rapid chromatographic immunoassay for the qualitative detection of COVID-19 antigen in saliva specimen to aid in the diagnosis of COVID- 19 viral infection.		
Classification	Others		

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

Applicable Standards:

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|----------------------------|----------------------------|------------------------|
| <i>EN ISO 13485:2016</i> | <i>EN ISO 18113-2:2011</i> | <i>EN 13612:2002</i> |
| <i>ISO 14971:2019</i> | <i>EN 13641:2002</i> | <i>ISO 23640:2015</i> |
| <i>EN ISO 18113-1:2011</i> | <i>ISO 15223-1:2016</i> | <i>EN 62366-1:2015</i> |



Name Of Authorized Signatory	Angela Liu
Position Held In The Company	General Manager
Signature	<i>Angela</i>
Date	February 7, 2021
Place	Suzhou, China
Seal (Manufacturer)	