EC Declaration of Conformity

Manufacturer:

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

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E-mail:info@multibrands.eu.com

Whose Authorized Representative:

Name: Lotus NL B.V.

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

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 Combined (IgM/IgG/Neutralising antibody) Rapid Test (Colloidal Gold)	**Code&package Specification**	PDNVAT-U 24Tests/inner box 288Tests/outer carton
Intended Use	The product is used for the qualitative detection of human veins in whole blood, serum or plasma samples of Corona Virus (COVID-19) IgM/IgG/Neutralizing antibody. The results of this kit are only for clinical reference. Comprehensive analysis of the patient's condition should be carried out in combination with clinical symptoms and other laboratory tests.		
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

CE

Name Of Authorized Signatory	Angela Liu
Position Held In The Company	General Manager
Signature	Angela 2021.02.07
Date	February 7, 2021
Place	Suzhou, China.
Seal (Manufacturer)	