EC Declaration of Conformity

Manufacturer:
Name: Multibrands Trading (Suzhou) Co., Ltd.
Address: Room 313, No. 58 Ruiyuan Building, Dongda Street, Gusu District, Suzhou, Jiangsu, China.
Tel: +86-512-82289188
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, the manufacturer, here with declare that the product(s)

Product Name	SARS-CoV-2 Antigen Rapid Qualitative Test	**Model:**	PDRTKTA-U
Intended Use	The COVID-19 Antigen Rapid Test Cassette is a lateral ow immunoassay intended for the qualitative detection SARS-CoV-2 nucleocapsid antigens in nasopharyngeal swab and oropharyngeal swab from individuals who are suspected of COVID-19 by their healthcare provider. Results are for the identi-cation of SARS-CoV-2 nucleocapsid antigen. Antigen is generally detectable in nasopharyngeal swab and oropharyngeal swab during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status.		
Classification	Others		

Conformity Assessment Route: IVDD98/79/EC Annex III.

Applicable Standards:

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

We, the manufacturer, here declare with sole responsibility that our product/s 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 agree to develop,implement and maintain a documented post-production monitoring process.

Name of General Manager	Angela Liu
Signature	Angela
Date	2020/11/17
Place	Suzhou, China
Seal (Manufacturer)	