EC Declaration of Conformity

Manufacturer:

Name: Jiangsu Mole Bioscience Co., Ltd.

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Whose Authorized Representative:

Name: Lotus NL B.V.

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

E-mail: peter@lotusnl.com

We, Jiangsu Mole Bioscience 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 Jiangsu Mole Bioscience Co., Ltd. (Manufacturer).

Product Name	SARS-CoV-2 Antigen Test Cassette	**Packaging Specification**	20 Tests/Kit
Intended Use	The SARS-CoV-2 Antigen Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of severe acute respiratory syndrome coronavirus 2(SARS-CoV-2) antigens in nasal swab and saliva specimens from human. The test is intended to aid in the rapid differential diagnosis of SARS-CoV-2 viral infection.		
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	Linfu Zhou
Position Held In The Company	General Manager
Signature	Linfu Zhou
Date	April 28, 2021
Place	Taizhou, China.
Seal (Manufacturer)	Jiangsu Mole Bioscience Co., Ltd.