EC Declaration of Conformity

Manufacturer:
Name: Innova Medical Group, Inc.
Address:718 S. Primrose Ave, Monrovia, California , USA.
Tel: +1(626)-239 0025
Fax: +1(626)-239 0038
Web:www.innovamedgroup.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	Innova SARS-CoV-2 Antigen Rapid Qualitative Test	**Specification**	25Tests/Kit
Intended Use	The Innova SARS-CoV-2 Antigen Rapid Qualitative Test is a colloidal gold immunochromatography intended for the qualitative detection of nucleocapsid antigens from SARS-CoV-2 in human nasal swabs, throat swabs, and sputum from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms.		
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	Charles C. Huang
Signature	
Date	September 7th, 2020
Place	California , USA.
Seal (Manufacturer)	C Huang