EC Declaration of Conformity

Manufacturer: PHASE Scientific International Limited
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Authorized Representative:
Name: Lotus NL B.V.
Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.
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We, the manufacturer, here with declare that the product(s)

Product Name	**PHASIFY™ DeCOVID SARS-CoV-2 RT-qPCR Kit**	**Specification**	IVD
Intended Use	The PHASIFY™ DeCOVID SARS-CoV-2 RT-qPCR Kit is a RT-qPCR kit for detecting SARS-CoV-2 from human respiratory specimens, including nasopharyngeal swabs, oropharyngeal swabs and sputum.		
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 Product Director	Kent Cheng, Ph.D.
Signature	
Date	20 October 2020
Place	Hong Kong, China.
Seal (Manufacturer)	