

EC Declaration of Conformity

Manufacturer: PHASE Scientific International Limited
Name: Kent Cheng, Ph.D.
Address: 32F, Gravity, 29 Hing Yip St., Kwun Tong, KLN, HK
Tel: +852 3892 7200
E-Mail: info@phasesci.com

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	PHASIFY™ Sample Collection Kit (Swab)	Specification	IVD
Intended Use	The PHASIFY™ VIRAL Sample Collection Kit (Swab) is intended for the collection, preservation, stabilization, and transportation of viral RNA collected from human nasal anterior nares, oropharyngeal, and nasopharyngeal swab samples for molecular testing.		
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



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)	

