

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: Emergo Europe
Address: Prinsessegracht 20,
2514 AP, The Hague, Netherlands.

We, the manufacturer, here with declare that the product(s)

Product Name	PHASIFY™ VIRAL RNA Extraction Kit	Specification	IVD
Intended Use	The PHASIFY™ VIRAL RNA Extraction Kit is designed for maximum yield of viral RNA from viral transport media samples (including PBS and saline). The product has demonstrated superior recovery against solid phase extraction methods.		
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	13 July 2020
Place	Hong Kong, China.
Seal (Manufacturer)	

