

# EC Declaration of Conformity

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

<b>Product Name</b>	<b>PHASIFY™ DeCOVID SARS-CoV-2 RT-qPCR Kit</b>	<b>Specification</b>	IVD
<b>Intended Use</b>	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.		
<b>Classification</b>	Others		

**Conformity Assessment Route :** IVDD98/79/EC Annex III.

#### Applicable Standards:

ISO 13485:2016  
ISO 14971:2019  
EN ISO 18113-1:2011

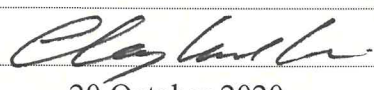
EN ISO 18113-2:2011  
EN 13641:2002  
ISO 15223-1:2016

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.

<b>Name of Product Director</b>	Kent Cheng, Ph.D.
<b>Signature</b>	
<b>Date</b>	20 October 2020
<b>Place</b>	Hong Kong, China.
<b>Seal (Manufacturer)</b>	

