EU Declaration of Conformity

We:		Authorized Representative:	
▪ **Company Name:**	Guangzhou Pluslife Biotech Co., Ltd.	▪ **Company Name:**	Kingsmead Service B.V.
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The EU Declaration of Conformity is issued under the sole responsibility regarding the following product:

▪ **Product Name:**	SARS-CoV-2 Nucleic Acid Testing Card
▪ **Brand Name:**	Pluslife SARS-CoV-2 Card
▪ **Product Code:**	RM1010202-1, RM1010202-2, RM1010202-5, RM1010202-10, RM1010202-20, RM1010202-50.
▪ **Intended Use**	The SARS-CoV-2 Nucleic Acid Testing Card is used for in vitro qualitative detection of the N gene and ORF1ab gene of novel coronavirus SARS-CoV-2 in nasal swab samples from suspected pneumonia cases of SARS-CoV-2 infection and suspected cluster cases and other persons requiring diagnosis or differential diagnosis of SARS-CoV-2 infection. The test results are only for clinical reference and shall not be used as the sole standard for clinical diagnosis. A comprehensive analysis of the patient's clinical manifestations and other laboratory tests is recommended.
▪ **Classification**	Devices other than self-testing devices or devices appearing in Annex II.
▪ **Conformity Assessment Procedure**	Annex III of European In vitro diagnostic medical devices Directive 97/89/EC.

We hereby declare that the above-mentioned products meet the Annex I (Essential Requirement) and provisions of the European In vitro diagnostic medical devices Directive 97/89/EC and below Harmonized Standards.

- EN ISO 13485:2016+A1:2021
- EN 13612:2002
- EN ISO 18113-1:2011
- EN ISO 14971:2019
- EN ISO 23640:2015
- EN ISO 18113-2:2011

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