DECLARATION OF CONFORMITY

ACCORDING TO In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Device Classification

Classification: Class A.

Rule: According to Rule 5, Annex VIII, of In Vitro Diagnostic Medical Devices Regulation (EU)2017/746.

Applicable Standards

EN ISO 20417: 2021
EN ISO 15223-1:2021
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 14971:2019

Manufacturer

Name: Hangzhou LifeReal Biotechnology Co.,Ltd.
Address: The 3rd, 4th, 5th, 8th Floor of Building No.3 and the 4th Floor of Building No.9, Hexiang Science and Technology Center, Qiantang New District, Hangzhou City, Zhejiang Province, China
SRN: CN-MF-000019191

Product Information

Name: Real-Time Fluorescence Quantitative PCR system
Specification: QuantReady K9600
EMDN: W02050301
GMDN: 48031
Basic UDI-DI:
Classification: Class A

Conformity Assessment

Compliance of the designated product with the In Vitro Diagnostic Medical Devices Regulation (EU)2017/746 has been assessed by issuing the EU declaration of conformity referred to in Article 17 after drawing up the technical documentation set out in Annexes II and III.

Remark

The declaration of conformity is valid in connection with the release technical document CE/IVDR- W02050301-01.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Declaration

We herewith declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 and the applicable standards above.

Signature: Date: Sep 26, 2022

Position: GM Place: Hangzhou/China