CE-DOC-H009
Version 2.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: *Healgen Scientific Limited Liability Company*

Legal Manufacturer Address: *3818 Fuqua Street, Houston, TX 77047, USA*

Declares, that the products
Product Name and Model(s)

Syphilis Ab Rapid Test Strip (Serum/Plasma)	GCSYP-301a
Syphilis Ab Rapid Test Cassette (Serum/Plasma)	GCSYP-302a
Syphilis Ab Rapid Test Strip (Whole Blood/Serum/Plasma)	GCSYP-401a
Syphilis Ab Rapid Test Cassette (Whole Blood/Serum/Plasma)	GCSYP-402a

Classification: *Other*
Conformity assessment route: *Annex III (EC DECLARATION OF CONFORMITY)*

We, the Manufacturer, herewith 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 hereby explicitly appoint

EC Representative's Name: QARAD BV

EC Representative's Address: Cipalstraat 3, 2440 Geel, BELGIUM

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned, hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements.

Date Signed: March 4, 2022

Name of authorized signatory: Joyce Pang
Position held in the company: Vice-President