3818 Fuqua street
Houston, TX 77047, USA
Tel: +1 713 733 8088
Fax: +1 713 733 8848
Web: www.Healgen.com
E-mail: sales@healgen.com

CE-DOC-H001
Ver.1.9

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)

Orient Gene HIV 1/2 Human Immunodeficiency Virus Rapid Test (Serum/Plasma)(Cassette)	GCHIV-302a
Orient Gene HIV 1/2 Human Immunodeficiency Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette)	GCHIV-402a

EDMA Code: 15 70 03 02

Classification: *Annex II List A*
Conformity assessment route: *Annex IV (Full Quality Assurance)*

Compliance of the designated product with the Directive 98/79/EC has been assessed and certified by the Notified Body
Notified Body: TÜV SÜD Product Service GmbH
Notified Body Address: Munich Branch Ridlerstraße 65 80339 München Germany
EC Certificate No.: V1 092378 0004 Rev 02 Valid until: 2025-05-26
EC Design-Examination Certificate No.: V7 092378 0006 Rev.02 Valid until: 2025-05-26

It bears the mark

CE 0123

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 Name: QARAD b.v.b.a.
EC Representative Address: Cipalstraat 3, B-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

Signature: Joyce Pang
Name of authorized signatory: Joyce Pang
Position held in the company: Vice-President
Date: 2022.3.25