浙江东方基因生物制品股份有限公司
Zhejiang Orient Gene Biotech Co.,LTD

CE-DOC-OG019
Version 7.0

CE

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: *Zhejiang Orient Gene Biotech Co., Ltd*

Legal Manufacturer Address: *3787#, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China.*

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

Healgen Chlamydia Trachomatis Antigen Rapid Test (Cassette) (Swab/Urine)	GCCHL-502a

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

Notified Body' Name: TÜV SÜD Product Service GmbH
Notified Body Address: Ridlerstraße 65 80339 München Germany
Notified Body ID: 0123
EC Certificate Registration number: V1 092305 0002 Rev.01
Expiry date of EC certificate: 2025-04-07

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: May 12, 2022

Joyce Pang

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