



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



CE-DOC-OG053-1  
Version 1.0

# 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)

*See attachment*

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:** Shanghai International Holding Corp. GmbH (Europe)

**EC Representative's Address:** Eiffestrasse 80, 20537 Hamburg, Germany

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: October 13<sup>th</sup>, 2020

Name of authorized signatory: Joyce Pang

Position held in the company: Vice-President



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

Attachment to CE-DOC-OG053-1 Version 1.0

Urinalysis Strips	URS-1T
Urinalysis Strips	URS-2T
Urinalysis Strips	URS-3T
Urinalysis Strips	URS-4T
Urinalysis Strips	URS-5T
Urinalysis Strips	URS-6T
Urinalysis Strips	URS-7T
Urinalysis Strips	URS-8T
Urinalysis Strips	URS-9T
Urinalysis Strips	URS-10T
Urinalysis Strips	URS-11T
Urinalysis Strips	URS-12T
Urinalysis Strips	URS-13T
Urinalysis Strips	URS-14T