



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



CE-DOC-OG060  
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)

Fecal Occult Blood Rapid Test Strip (Feces)	GEFOB-601b
Fecal Occult Blood Rapid Test Cassette (Feces)	GEFOB-602b

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: November 28, 2017

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