



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



CE-DOC-OG038
Version 2.0

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)

Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma)	GDTRO-402a
Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma)	GDTRO-402b

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: August 11, 2020

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