



EC DECLARATION OF CONFORMITY

According to the *In Vitro* Diagnostic Medical Device Directive 98/79/EC

No.: DOC-W216(1)-01

Version: 00

Manufacturer:

Guangzhou Wondfo Biotech Co., Ltd.

Address:

No.8, Lizhishan Road, Science City, Luogang District,
510663, Guangzhou, P.R. China

EC Authorised Representative: Qarad BV

Address:

Cipalstraat 3, 2440 Geel, Belgium

***In Vitro* Diagnostic Medical Device(s):**

Product Name: Finecare™ cTnI/CK-MB/Myo Rapid Quantitative Test

Cat. No.: W216

IVDD Classification: Other, for professional use

This declaration of conformity is issued under the sole responsibility of the manufacturer that the above product(s) meet(s) the provisions of the European Directive 98/79/EC for *In Vitro* Diagnostic Medical Devices and Regulation (EC) No 1272/2008.

The following (harmonized) standards have been applied:

EN ISO 13485:2016

EN ISO 18113-1:2011

EN 13612:2002

EN ISO 14971:2019

EN ISO 18113-2:2011

EN 13641:2002

EN ISO 23640:2015

EN ISO 15223-1:2016

EN 62366-1:2015

EN ISO 17511:2003

The conformity with the requirements of the Directive has been assessed following the procedure(s) outlined in the following annexes of the Directive: **Annex III, excluding 6**

Notified Body (if consulted): Not Applicable

Address:

/

EC Certificate(s):

/

Expiry date of the Certificate(s):

/

Signature of manufacturer

(Name and function):

Senior President of Regulatory Affairs

Place and date of issue:

Guangzhou, P.R. China,

March 11, 2022