EC DECLARATION OF CONFORMITY
According the In Vitro Diagnostic Medical Device Directive 98/79/EC

Manufacturer:	Guangzhou Wondfo Biotech Co., Ltd.
Address:	No.8, Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, P.R. China

In vitro diagnostic device(s):

Product Name	Cat. No.	IVDD Classification
Finecare™ PCT Control	W805-L, W805-M, W805-H	Other, for professional use
Finecare™ CRP Control	W806-L, W806-M, W806-H	Other, for professional use
Finecare™ NT-proBNP Control	W807-L, W807-M, W807-H	Other, for professional use
Finecare™ Troponin I Control	W808-L, W808-M, W808-H	Other, for professional use
Finecare™ Myo Control	W809-L, W809-M, W809-H	Other, for professional use
Finecare™ CK-MB Control	W810-L, W810-M, W810-H	Other, for professional use
Finecare™ H-FABP Control	W811-L, W811-M, W811-H	Other, for professional use
Finecare™ D-Dimer Control	W812-L, W812-M, W812-H	Other, for professional use
Finecare™ MAU Control	W813-L, W813-M, W813-H	Other, for professional use
Finecare™ Prostate Specific Antigen Control	W814-L, W814-M, W814-H	List B of Annex II
FinecareTM Alpha-fetoprotein Control	W815-L, W815-M, W815-H	Other, for professional use
Finecare™ Cystatin C Control	W816-L, W816-M, W816-H	Other, for professional use
Finecare™ cTnI/CK-MB/Myo Multi-Control	W817	Other, for professional use
Finecare™ CRP/PCT Multi-Control	W818-L, W818-M, W818-H	Other, for professional use
Finecare™ β-hCG Control	W819-L, W819-M, W819-H	Other, for professional use
Finecare™ Carcino-embryonic Antigen Control	W820-L, W820-M, W820-H	Other, for professional use
Finecare™ cTnI/NT-proBNP Multi-Control	W821-L, W821-M, W821-H	Other, for professional use

This declaration of conformity is issued under the sole responsibility of the manufacturer that that the above product(s) meet(s) the provisions of the European Directive 98/79/EC for *in vitro* Diagnostic Medical Devices.

The following (harmonized) standards have been applied:

Digitally signed by Varman Irina
Date: 2021.12.27 13:17:43 EET
Reason: MoldSign Signature
Location: Moldova

EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 15223-1:2016
EN ISO 13485:2012	EN ISO 17511:2003	EN ISO 14971:2012
EN 13612:2002	EN 13641:2002	EN ISO 23640:2015
EN 62366:2008	EN 61010-1:2001	EN 61010-2-101:2002
EN 61326-1:2006	EN 61326-2-6:2006	

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, Annex IV, excluding 4 and 6**

Notified Body(if consulted):	EC Certificate number V1 18 01 58008 024 has been issued by the Notified Body: **TÜV SÜD Product Service GmbH (NB#0123)** Ridlerstraβe 65, D-80339 München

Technical documentation demonstrating compliance is kept by the manufacturer and can be made available by the authorized representative in Europe:

Qarad b.v.b.a., Cipalstraat 3, B-2440 GEEL, Belgium

Guangzhou. Nov. 29, 2018	Amy Lee Amy Lee, Management Representative
(Place and date of issue)	(name and signature or equivalent marking of authorized person)