Wondfo

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):	/

Digitally signed by Varman Irina
Date: 2024.02.01 19:31:47 EET
Reason: MoldSign Signature
Location: Moldova

Signature of manufacturer

(Name and function): Senior President of Regulatory Affairs

Place and date of issue: Guangzhou, P.R. China,

March 11, 2022

Wondfo

EC DECLARATION OF CONFORMITY

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

Document No.: DOC-W209(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™ PSA Rapid Quantitative Test
Cat. No.:	W209
IVDD Classification:	List B of Annex II, 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 14971:2012	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 IV, excluding 4 and 6**

Notified Body (if consulted):	**TÜV SÜD Product Service GmbH (NB # 0123)**
Address:	Ridlerstraße 65, D-80339 München
EC Certificate(s):	V1 058008 0030 Rev.01
Expiry date of the Certificate(s):	2025-05-26

Signature of manufacturer

(Name and function): Bin Yang, Senior Vice President of Regulatory Affairs

Place and date of issue: Guangzhou, P.R. China,

April 20, 2022

Wondfo

EC DECLARATION OF CONFORMITY

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

No.: DOC-W208(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™ AFP Rapid Quantitative Test
Cat. No.:	W208
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

Wondfo

EC DECLARATION OF CONFORMITY

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

No.: DOC-W203(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™ cTn I Rapid Quantitative Test
Cat. No.:	W203
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

Wondfo

EC DECLARATION OF CONFORMITY

According to 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
EU Authorised Representative:	**Qarad BV**
Address:	Cipalstraat 3, 2440 Geel, Belgium

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

Product Name:	Finecare™ FIA Meter II Plus SE
Cat. No.:	FS-114
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.

The following (harmonized) standards have been applied:

EN ISO 13485:2016	EN ISO 14971:2019	EN ISO 15223-1:2016
EN 13612:2002	EN ISO 18113-1:2011	EN ISO 18113-3:2011
EN 62304:2006	EN 62366-1: 2015	EN 61010-1: 2010+A1:2019
EN 61010-2-101:2017	EN 62133-2:2017	EN 61326-1:2013
EN 61326-2-6:2013	EN IEC 62311:2020	EN 61010-2-081:2015
ETSI EN 301 489-17 V3.2.4(2020-09)	ETSI EN 300 328 V2.2.2(2019-07)	ETSI EN 301 489-1 V2.2.3(2019-11)

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): Lingfang Huang

Lingfang Huang, Vice President of Regulatory Affairs

Issue date: 2021-08-20