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): | / |

Signature of manufacturer

(Name and function): Senior President of Regulatory Affairs

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

March 11, 2022

Digitally signed by Varman Irina
Date: 2024.01.30 18:53:00 EET
Reason: MoldSign Signature
Location: Moldova

Wondfo

# EC DECLARATION OF CONFORMITY

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

No.: DOC-W201(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™ CRP Rapid Quantitative Test |
| Cat. No.: | W201, W201P0008 |
| 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-W211(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™ D-Dimer Rapid Quantitative Test |
| Cat. No.: | W211 |
| 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

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 |
| **EC Authorised Representative:** | **Qarad BV** |
| Address: | Cipalstraat 3, 2440 Geel, Belgium |

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

| | |
|---|---|
| Product Name: | Finecare™ FIA Meter Plus |
| Model No.: | FS-113 |
| 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, Directive 80/181/EEC and RoHS Directive 2011/65/EU.

The following (harmonized) standards have been applied:

| | | |
|---|---|---|
| EN ISO 13485:2016 | EN 61010-1: 2010 | EN 13612:2002 |
| EN ISO 14971:2019 | EN 61010-2-081:2015 | EN 62304:2006 |
| EN ISO 18113-1:2011 | EN 61010-2-101:2002 | EN 62366-1:2015 |
| EN ISO 18113-3:2011 | EN 61326-2-6: 2013 | EN 61326-1: 2013 |
| EN ISO 15223-1:2016 | EN 62321 Series | |

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):

Vice-President of Regulatory Affairs

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

December 10, 2021

Wondfo

# EC DECLARATION OF CONFORMITY

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

Document No.: DOC-W210(2)-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™ PCT Rapid Quantitative Test |
| Cat. No.: | W210P0004 |
| 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): 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-W202(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™ NT-proBNP Rapid Quantitative Test |
| Cat. No.: | W202 |
| 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