

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

Document No.: DOC-W819(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™ β-hCG Control**Cat. No.:** W819**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

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:**

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**EC Certificate(s):**

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**Expiry date of the Certificate(s):**

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**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