

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

Document No.: DOC-W873(1)-01

Version: 00

Manufacturer: **Guangzhou Wondfo Biotech Co., Ltd.**
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510663, Guangzhou, P.R. China

EC Authorised Representative: Qarad BV
Address: Ciplastraat 3, 2440 Geel, Belgium

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

Product Name: Finecare™ HbA1c Control
Cat. No.: W873P0001
IVDD Classification: Other, for professional use

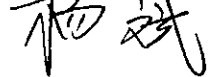
This declaration of conformity is issued under the sole responsibility of the manufacturer that the above product(s) meet(s) the provisions of the European Directive 98/79/EC for *In Vitro* Diagnostic Medical Devices and Regulation (EC) No 1272/2008.

The following (harmonized) standards have been applied:

EN ISO 13485:2016	EN ISO 18113-1:2011	EN 13612:2002
EN ISO 14971:2012	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: /
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