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: Wondfo® Optical Coagulation Analyzer
Cat. No.: OCG-102
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 18113-1:2011	EN ISO 18113-3:2011	EN ISO 15223-1:2016
EN ISO 14971: 2019	EN 61010-1:2010 +A1:2019	EN 61010-2-101:2017
EN 61326-1:2013	EN 61326-2-6:2013	EN 62366-1:2015
EN 301 489-17 V3.1.1	EN 301 489-1 V2.1.1	EN 300 328 V2.1.1
EN ISO 13485: 2016	EN 62311: 2008	EN 13612: 2002

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: 2025.02.20 12:32:38 EET
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Signature of manufacturer (Name and function):

Lingfang Huang, Vice-President of Regulatory Affairs

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Lingfang Huang