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

Digitally signed by Cobzari-Turcan Rodica
Date: 2024.04.18 15:05:16 EEST
Reason: MoldSign Signature
Location: Moldova

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

No.	Product Name:	Model:
1	One Step Multi-Drug Urine Test (+Adulteration and Alcohol) Panel	W55102-P, W55103-P, W55104-P, W55105-P, W55106-P, W55107-P, W55108-P, W55109-P, W55110-P, W55111-P, W55112-P
2	One Step Multi-Drug Urine Test (+Adulteration and Alcohol) T-cup	W55102-CU2, W55103-CU2, W55104-CU2, W55105-CU2, W55106-CU2, W55107-CU2, W55108-CU2, W55109-CU2, W55110-CU2, W55111-CU2, W55112-CU2, W55113-CU2, W55114-CU2, W55115-CU2, W55116-CU2, W55117-CU2, W55118-CU2
3	One Step Multi-Drug Urine Test (+Adulteration and Alcohol) Q-cup	W55102-CU3, W55103-CU3, W55104-CU3, W55105-CU3, W55106-CU3, W55107-CU3, W55108-CU3, W55109-CU3, W55110-CU3, W55111-CU3, W55112-CU3, W55113-CU3, W55114-CU3, W55115-CU3, W55116-CU3, W55117-CU3, W55118-CU3
4	One Step Multi-Drug Urine Test Panel for Analyzer	W501-P, W502-P, W503-P, W504-P, W505-P, W506-P, W507-P, W508-P, W509-P, W510-P
5	One Step Multi-Drug Urine Test Panel	W2002-P, W2003-P, W2004-P, W2005-P, W2006-P, W2007-P, W2008-P, W2009-P, W2010-P, W2011-P, W2012-P, W2013-P, W2014-P, W2015-P, W2016-P
6	One Step Multi-Drug Urine Cup	W2002-CU, W2003-CU, W2004-CU, W2005-CU, W2006-CU, W2007-CU, W2008-CU, W2009-CU, W2010-CU,

		W2011-CU, W2012-CU
7	One Step Multi-Drug Urine T-Cup	W502-CU2, W503-CU2, W504-CU2, W505-CU2, W506-CU2, W507-CU2, W508-CU2, W509-CU2, W510-CU2, W511-CU2, W512-CU2, W513-CU2, W514-CU2, W515-CU2, W516-CU2, W517-CU2, W518-CU2
8	One Step Multi-Drug Urine Q-Cup	W502-CU3, W503-CU3, W504-CU3, W505-CU3, W506-CU3, W507-CU3, W508-CU3, W509-CU3, W510-CU3, W511-CU3, W512-CU3, W513-CU3, W514-CU3, W515-CU3, W516-CU3, W517-CU3, W518-CU3
9	One Step Multi-Drug Urine T-Cup Plus	W502-CU7, W503-CU7, W504-CU7, W505-CU7, W506-CU7, W507-CU7, W508-CU7, W509-CU7, W510-CU7, W511-CU7, W512-CU7, W513-CU7, W514-CU7, W515-CU7, W516-CU7, W517-CU7, W518-CU7
10	One Step Multi-Drug Urine Q-Cup Plus	W502-CU8, W503-CU8, W504-CU8, W505-CU8, W506-CU8, W507-CU8, W508-CU8, W509-CU8, W510-CU8, W511-CU8, W512-CU8, W513-CU8, W514-CU8, W515-CU8, W516-CU8, W517-CU8, W518-CU8
11	One Step Multi-Drug Oral Fluid T-Cube	W602-CU6, W603-CU6, W604-CU6, W605-CU6, W606-CU6, W607-CU6, W608-CU6, W609-CU6, W610-CU6

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 ISO 18113-1:2011	EN ISO 18113-2:2011	EN 13612:2002
EN ISO 23640:2015	EN 13641:2002	EN 62366:2008

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): /

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Signature of manufacturer (Name and function): Lingfang Huang

Lingfang Huang, Vice-President of Regulatory Affairs

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