

DECLARATION OF CONFORMITY

According to the Principles of Conformity Assessment for In Vitro Diagnostic (IVD)
Medical Devices *GHTF/SG1/N046:2008*

Document No.:DOC-W006(1)-01

Version: 01

Manufacturer:**Guangzhou Wondfo Biotech Co., Ltd.**

Address:

No.8, Lizhishan Road, Science City, Huangpu District,
510663, Guangzhou, P.R. China***In Vitro* Diagnostic Medical Device(s):**

Product name: One Step HIV1/2 Whole Blood/Serum/Plasma Test
Cat. No.: W006-C4P2 (25 Tests/kit) W006-C4P2-F (40 Tests/Kit)
W006-P0045 (25 Tests/kit) W006-P0049 (40 Tests/kit)
W006-P0046 (25 Tests/kit) W006-P0050 (40 Tests/kit)
W006-P0047 (25 Tests/kit) W006-P0051 (40 Tests/kit)
W006-P0048 (25 Tests/kit) W006-P0052 (40 Tests/kit)

Risk-based Classification: Class D

Classification rule:

Rule 1

(According to *Principles of In Vitro Diagnostic (IVD) Medical
Devices Classification IMDRF/IVD WG/N64FINAL:2021*)

GMDN code:

65847

This declaration of conformity is issued under the sole responsibility of the manufacturer that the above product(s) meet(s) the provisions of the *GHTF Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices GHTF/SG1/N046:2008*.

The following standards have been applied:

ISO 13485:2016

ISO 18113-1:2022

IEC 62366-1:2015

ISO 14971:2019

ISO 18113-2:2022

ISO 15223-1:2021

ISO 23640:2011

The conformity with the requirements of the Principles has been assessed following the procedure(s) outlined in the *GHTF Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices GHTF/SG1/N046:2008*.

Quality Management System Certificate:

Conformity Assessment Body issuing the certificate:

TÜV SÜD Product Service GmbH

Certificate number:

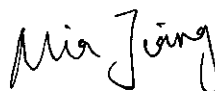
No. Q5 058008 0025 Rev.05

Issuance date:

2024-02-01

Expiry date:

2027-01-31

Signature of manufacturer

(Name and function):

Mia Jiang, Regulatory Affairs Manager

Place and date of issue:

Guangzhou, P.R. China

January 25, 2024