World Health Organization

# WHO list of prequalified in vitro diagnostic products

**RoW: Rest of the world**. Regulatory version applied to products not approved by stringent/mature NRAs or not regulated

Last update: 22 February 2022

| Year prequalified | Type of assay | Product name | Product code(s) | Regulatory version | Manufacturer | Manufacturing site(s) | Packaging |
|---|---|---|---|---|---|---|---|
| 2018 | Malaria RDT | First Response Malaria Antigen P. *falciparum* (HRP2) Card Test | PI13FRC25 | RoW | Premier Medical Corporation Limited | India;<br>**site 2:** 32-35A, Shree Ganesh Industrial Estate, Kachigam, Nani Daman, Daman 396215, India | 25 × multi kit |
| | | | PI13FRC30 | | | | 30 × multi kit |
| 2018 | Malaria RDT | First Response Malaria Ag. pLDH/HRP2 Combo Card Test | PI16FRC10s | RoW | Premier Medical Corporation Limited | **site 1**: A1-302, GIDC, Sarigam 396 155, Valsad, Gujarat, India;<br>**site 2**: 32-35A, Shree Ganesh Industrial Estate, Kachigam, Nani Daman, Daman 396215, India | 10 × single kit |
| | | | PI16FRC25s | | | | 25 × single kit |
| | | | PI16FRC25 | | | | 25 × multi kit |
| | | | PI16FRC30 | | | | 30 × multi kit |
| 2018 | Malaria RDT | First Response Malaria Ag. P.f. / P.v. Card Test | PI19FRC10s | RoW | Premier Medical Corporation Limited | **site 1**: A1-302, GIDC, Sarigam 396 155, Valsad, Gujarat, India;<br>**site 2**: 32-35A, Shree Ganesh Industrial Estate, Kachigam, Nani Daman, Daman 396215, India | 10 × single test |
| | | | PI19FRC25s | | | | 25 × single test |
| | | | PI19FRC30 | | | | 30 × multi test |
| | | | PI19FRC25 | | | | 25 × multi test |
| 2018 | Malaria RDT | *Bioline Malaria Ag P.f/P.f/P.v | 05FK120;<br>05FK123 | CE-mark | Abbott Diagnostics Korea Inc | 65 Borahagal-ro, Giheung-gu, Yongin-si, Geonggi-do, South Korea | 25T/kit;<br>1T/kit |
| 2018 | HIV RDT for self-testing | *INSTI HIV Self Test | 90-1071 | RoW | bioLytical Laboratories Inc. | Richmond, British Columbia, Canada | 1T/kit |
| 2018 | HIV RDT | *One Step HIV1/2 Whole Blood/Serum/Plasma Test | W006-C4P2,<br>W006-P0045,<br>W006-P0046,<br>W006-P0047,<br>W006-P0048,<br>W006-C4P2-F,<br>W006-P0049,<br>W006-P0050,<br>W006-P0051 ,<br>W006-P0052 | RoW | Guangzhou Wondfo Biotech Co., Ltd | 8 Lizhishan Road, Science City, Luogang District, Guangzhou, 510663, Republic of China | 25T/kit;<br>25T/kit;<br>25T/kit;<br>25T/kit;<br>25T/kit;<br>40T/kit;<br>40T/kit;<br>40T/kit;<br>40T/kit;<br>40T/kit |
| 2018 | Malaria RDT | *One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag | MFLRPD-02;<br>MFLRPD-03;<br>MFLRPD-04;<br>MFLRPD-05 | CE-marked | Meril Diagnostics Pvt. Ltd. | D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi 396191, Gujarat, India | 30T/kit;<br>25T/kit;<br>50T/kit;<br>10 T/kit. |
| 2018 | CD4 Technologies | *CyFlow Counter System with CD4 easy count kit and CD4% easy count kit | CY-S-3022; 05-8401; and 05-8405 | CE-marked | Sysmex Partec GmbH | **site 1**: Arndtstr. 11a-b, 02826 Görlitz, Germany; and **site 2**: Exbio Praha a.s., Nad Safinou II 341, 252 50 Vestec, Czech Republic | 100 T/kit |
| 2018 | HPV Virological Technologies | *care* HPV Test | 614015 | CE-mark | QIAGEN GmbH | **site 1:** QIAGEN Sciences, Germantown, 20874, United States<br>**site 2**: QIAGEN Shenzhen Co., Shenzhen China | 96 T/kit |
| 2018 | HCV EIA | INNOTEST HCV Ab IV | 80068;<br>80330 | CE-mark | Fujirebio Europe NV | Ghent, Belgium | 192T/kit<br>480T/kit |
| 2017 | HBsAg RDT | *Bioline HBsAg WB | 01FK10W | RoW | Abbott Diagnostics Korea Inc | Giheung-gu, Republic of Korea | 30T/kit |

Digitally signed by Matei Andrei
Date: 2022.06.06 13:37:58 EEST
Reason: MoldSign Signature
Location: Moldova

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

# EC Certificate

**EC Design-Examination Certificate**
**Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)**
**V7 058008 0027 Rev. 01**

**Manufacturer:** **GUANGZHOU WONDFO BIOTECH CO., LTD.**
No. 8 Lizhishan Road, Science City
Luogang District
510663 Guangzhou
PEOPLE'S REPUBLIC OF CHINA

**EC-Representative:** Qarad b.v.b.a
Cipalstraat 3, B-2440 GEEL, BELGIUM

**Product:** **Screening test for HIV-1/-2 marker**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex IV (4). The design of the devices conforms to the requirements of this Directive. See also notes overleaf.

**Report No.:** 713162896

**Valid from:** 2019-07-30
**Valid until:** 2024-03-04

**Date,** 2019-07-30

Stefan Preiß


TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

# Certificate

## No. Q5 058008 0025 Rev. 03

**Holder of Certificate:** GUANGZHOU WONDFO BIOTECH CO., LTD.
No. 8 Lizhishan Road, Science City
Luogang District
510663 Guangzhou
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**


**Scope of Certificate:** **Design and Development, Production, Distribution, Installation and Service of In Vitro Diagnostics for the Detection of Fertility, Pregnancy, Infectious Diseases, Drugs of Abuse, Tumor Markers, Cardiac Markers, Diabetes Markers, Renal Injury Markers, Autoimmune Diseases, Infection, Inflammation, Coagulation Factors, Blood Gas Markers and Related Instruments, Sperm Concentration Tests, Fluorescence Immunoassay Systems, Blood Glucose Monitoring Systems, Control Materials for Tumor Markers, Biochemical Reagents and Instruments**

The Certification Body of TÜV SÜD Product Service GmbH certif
ies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 058008 0025 Rev. 03

| | |
|---|---|
| **Report No.:** | SH2114101 |
| **Valid from:** | 2022-03-18 |
| **Valid until:** | 2024-01-31 |

**Date,** 2022-03-18

Christoph Dicks
Head of Certification/Notified Body


TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany