

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 Ag. P.f. / P.v. Card Test	PI13FRC25	RoW	Premier Medical Corporation Limited	India; 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	India; site 1: A1-302, GIDC, Sarigam 396 155, Valsad, Gujarat, India; 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	India; site 1: A1-302, GIDC, Sarigam 396 155, Valsad, Gujarat, India; 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.v	05FK120; 05FK123	CE-mark	Abbott Diagnostics Korea Inc	65 Borahagal-ro, Giheung-gu, Yongin-si, Geonggi-do, South Korea	25T/kit; 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, W006-P0045, W006-P0046, W006-P0047, W006-P0048, W006-C4P2-F, W006-P0049, W006-P0050, W006-P0051, W006-P0052	RoW	Guangzhou Wondfo Biotech Co., Ltd	8 Lizhishan Road, Science City, Luogang District, Guangzhou, 510663, Republic of China	25T/kit; 25T/kit; 25T/kit; 25T/kit; 25T/kit; 40T/kit; 40T/kit; 40T/kit; 40T/kit; 40T/kit
2018	Malaria RDT	*One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02; MFLRPD-03; MFLRPD-04; 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; 25T/kit; 50T/kit; 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	core HPV Test	614015	CE-mark	QIAGEN GmbH	site 1: QIAGEN Sciences, Germantown, 20874, United States site 2: QIAGEN Shenzhen Co., Shenzhen China	96 T/kit
2018	HCV EIA	INNOTEST HCV Ab IV	80068; 80330	CE-mark	Fujirebio Europe NV	Ghent, Belgium	192T/kit 480T/kit
2017	HBsAg RDT	*Bioline HBsAg WB	01FK10W	RoW	Abbott Diagnostics Korea Inc	Giheung-gu, Republic of Korea	30T/kit



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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 WONFEO 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



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 certifies 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

Christoph Dicks

Head of Certification/Notified Body

Date, 2022-03-18