

Product Service

EC Certificate

Full Quality Assurance System
Directive Regulation (EU) 2017/746 on
in Vitro Diagnostic Medical Devices, Annex IX, Chapter II, Section 4,5

No. V74 058008 0034 Rev. 00

Manufacturer: **GUANGZHOU WONDFO BIOTECH CO., LTD.**
No. 8 Lizhishan Road, Science City
Lougang District 510663 Guangzhou
SRN Manufacturer - CN-MF-000000689
People's Republic of China

Product Category(ies): **Finecare™ Fully-Automatic FIA Analyzer
(with the necessary reagents)**

The Certification Body of TÜV SÜD Product Service GmbH declares that of in vitro diagnostics as a medical device on the basis of the Classification Criteria (Annex II) of Directive Regulation (EU) 2017/746 on medical devices for in vitro diagnostics is subject to possible revisions of European regulations on the classification of medical devices and to advancing scientific understanding (See Chapter II, Section 4,5 of Directive Regulation (EU) 2017/746).

Report No.: 711492EX01

Valid from: 2021-08-12
Valid until: 2024-04-20

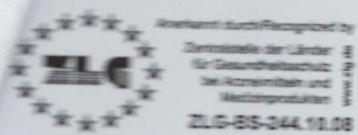
Date, 2021-08-12

Christoph Dicks
Head of Certification/Notified Body

促进委
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商事证明
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Facility(ies):

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People's Republic of China

Product:

Finecare™ Fully-Automatic FIA Analyzer

Reagent tests:

- | | |
|--|--|
| FT3 Rapid Quantitative Test | CRP Rapid Quantitative Test |
| FT4 Rapid Quantitative Test ✓ | cTn I Rapid Quantitative Test |
| NT-proBNP Rapid Quantitative Test | CK-MB Rapid Quantitative Test |
| Myo Rapid Quantitative Test | iFOB Rapid Quantitative Test |
| HbA1c Rapid Quantitative Test | PCT Rapid Quantitative Test |
| AFP Rapid Quantitative Test | cTnI/CK-MB/Myo Rapid Quantitative Test |
| D-Dimer Rapid Quantitative Test | CRP/PCT Rapid Quantitative Test |
| H-FABP Rapid Quantitative Test | TSH Rapid Quantitative Test |
| Cys C Rapid Quantitative Test | BNP Rapid Quantitative Test |
| SAA Rapid Quantitative Test | hs CRP Rapid Quantitative Test |
| cTn I/NT-proBNP Rapid Quantitative Test | CEA Rapid Quantitative Test |
| β-hCG Rapid Quantitative Test | NGAL Rapid Quantitative Test |
| B2-MG Rapid Quantitative Test | Estradiol (E2) Rapid Quantitative Test |
| T3 Rapid Quantitative Test | Progesterone Rapid Quantitative Test |
| T4 Rapid Quantitative Test | LH Rapid Quantitative Test |
| One Step D-Dimer Rapid Quantitative Test | Prolactin Rapid Quantitative Test |
| One Step cTnT Rapid Quantitative Test | Testosterone Rapid Quantitative Test |
| One Step NT-proBNP Rapid Quantitative Test | Ferritin Rapid Quantitative Test |
| One Step PCT Rapid Quantitative Test | AMH Rapid Quantitative Test |
| One Step MAU Rapid Quantitative Test | IL-6 Rapid Quantitative Test |
| One Step HIV-HCV-HBsAg-Syphilis Combo Test | FSH Rapid Quantitative Test |
| Vitamin D Rapid Quantitative Test | Cortisol Rapid Quantitative Test |

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