

dewei

Declaration of Conformity



Manufacturer:

DEWEI MEDICAL EQUIPMENT CO.,LTD

5th floor, No. 4 building, Shiyou Industrial Park, Jun'an, Shunde, Foshan, China

European Representative:

CMC Medical Devices & Drugs S.L.

C/ Horacio Lengo N° 18, CP 29006, Málaga, Spain

Product Name: See Attachment.

Model/Specification: See Attachment.

Classification:

According to directive 98/79/EC: Others devices

Conformity Assessment Route: IVDD 98/79/EC Annex III

We herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the following EC Council Directives and Standards. All technical documentations are retained under the premises of the manufacturer.

General applicable directive:

Directive 98/79/EC

Standards Applied:

EN ISO 23640:2015

EN ISO 15223-1:2016

EN 13612:2002

EN ISO18113-1:2011

EN ISO 14971:2012

EN ISO18113-2:2011

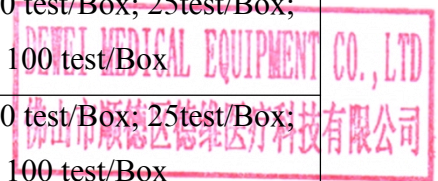
Signature: Managing Director

Place, Date of Issue: Foshan, Dec 30th, 2021

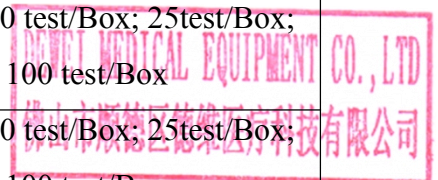
Dewei Medical Equipment Co.,Ltd

Attachment:

| Product Name | Model/Specification |
|---|---|
| Human Chorionic Gonadotropin (hCG) Pregnancy Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Luteinizing hormone (LH) Ovulation Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Follicle Stimulating Hormone (FSH) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Amphetamine (AMP) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Barbiturates (BAR) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Benzodiazepines (BZO) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Buprenorphine(BUP) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Caffeine(CFA) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Cocaine (COC) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Cotinine (COT) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Ethyl Glucuronide (ETG) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Fentanyl (FYL) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Ketamine(KET) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Marijuana (THC) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Methadone (MTD) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Methamphetamine (MET) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |



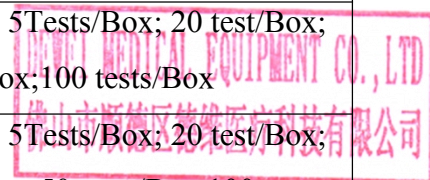
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| Methadone Metabolite (EDDP) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Methylenedioxymethamphetamine-ecstasy (MDMA) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Morphine (MOP) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Opiate (OPI) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Oxycodone (OXY) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Phencyclidine (PCP) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Propoxyphene (PPX) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Tri-cyclic Antidepressants (TCA) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| 6-Monoacetylmorphine (6-MAM) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Synthetic Cannabinoid (K2) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Tramadol (TRA) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Methaqualone (MQL) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Rapid Multi-Drug 2-12 Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Rapid Multi-Drug 2-15 Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Rapid Multi-Drug 13-15 Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Rapid Multi-Drug Test (Urine) | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Rapid Multi-Drug Test (Oral Fluid) | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| C-reactive Protein (CRP) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; |



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| | 40Tests/Box;50 test/Box; 100 test/Box |
| Cardiac Markers 3 in 1 Rapid Test Combo | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Troponin I (cTnI) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Heart Fatty Acid Binding Protein (h-FABP) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| NT-proBNP Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Alpha Fetal-protein (AFP) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| CK-MB Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Myoglobin Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| h-FABP/Troponin I Rapid Test Combo | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| h-FABP/Troponin I + CK-MB + Myoglobin Rapid Test Combo | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Procalcitonin (PCT) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| C-Reactive Protein Semi-Quantitative (HS-CRP) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| D-dimer Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Ferritin Rapid test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| FOB/Transferrin Rapid Test Combo | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Transferrin Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Microalbumin Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Carcinoembryonic Antigen (CEA) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |

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| Faecal Occult Blood (FOB) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Adenovirus Rapid Test | 1Test/Box;5Tests/Box; 20 test/Box; 25test/Box; 50 test/Box;100 test/Box |
| Rotavirus Rapid Test | 1Test/Box;5Tests/Box; 20 test/Box; 25test/Box; 50 test/Box;100 test/Box |
| Norovirus Antigen Rapid Test | 1Test/Box;5Tests/Box; 20 test/Box; 25test/Box; 50 test/Box;100 test/Box |
| Rotavirus and Adenovirus Rapid Test Combo | 1Test/Box;5Tests/Box; 20 test/Box; 25test/Box; 50 test/Box;100 test/Box |
| Malaria P.f/Pan Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Malaria P.f/P.v Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Malaria P.f. Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Dengue NS1 Antigen Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Dengue IgG/IGM Antibody Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Dengue NS1 & IgGIgM Rapid Test Combo | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| H.Pylori Antibody Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| H.Pylori Antigen Rapid Test (Feces) | 1Test/Box;5Tests/Box; 20 test/Box;25test/Box;50 test/Box;100 test/Box |
| Hepatitis A Virus (HAV) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Syphilis (Treponema Pallidum;TP) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Tuberculosis (TB) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Typhoid Fever Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Strep A (Group A Streptococci) Rapid | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; |

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| Test | 40Tests/Box;50 test/Box; 100 test/Box |
| Strep B (Group B Streptococci) Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Gonorrhea Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Monkeypox Virus IgM/IgG Antibody Rapid Test Kit | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Monkeypox Virus Antigen Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 50 test/Box; 100 test/Box |
| Influenza A+B Antigen Rapid Test Kit (Later Flow Assay) | 1Test/Box; 2Tests/Box; 5Tests/Box; 20 test/Box; 25tests/Box; 50 tests/Box; 100 tests/Box |
| COVID-19/Influenza A+B Antigen Rapid Test Kit (Later Flow Assay) | 1Test/Box;2Tests/Box; 5Tests/Box; 20 test/Box; 25tests/Box; 50 tests/Box;100 tests/Box |
| Covid-19 (2019-nCoV) Antigen Rapid Test Cassette | 1Test/Box;2Tests/Box; 5Tests/Box; 20 test/Box; 25tests/Box; 50 tests/Box;100 tests/Box |
| COVID-19 (2019-nCoV) Neutralizing Antibody Test Kit | 1Test/Box;2Tests/Box; 5Tests/Box; 20 test/Box; 25tests/Box; 40tests/Box; 50 tests/Box;100 tests/Box |
| COVID-19 (2019-nCoV) IgG/IgM Rapid Test Cassette | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Alcohol Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Astrovirus Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Brucellosis Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Calprotectin Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Chagas Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Chikungunya Virus (ChikV) IgG/IgM Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Ebola Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |



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| Filariasis IgM/IgG Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Herpes Simplex Virus (HSV 1/2) Antigen Antigen Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Herpes Simplex Virus (HSV-2) IgG Antibody Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Herpes Simplex Virus (HSV-2) IgM Antibody Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Leishmania IgM/IgG Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Vibrio Cholerae O1/O139 Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Vitamin D Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Zika Virus IgG/IgM Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |
| Zika NS1 Antigen Rapid Test | 1Test/Box; 5Tests/Box; 20 test/Box; 25test/Box; 40Tests/Box;50 test/Box; 100 test/Box |

