

CERTIFICATE OF IVD NOTIFICATION



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Annex A - List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

| # | Catalogue reference number | Commercial Name | Generic Device Term | Short description and intended use | GMDN/EDMS Code | Class |
|----|----------------------------|---|--|--|----------------|--------|
| 1. | FPRR009 | i-Chamber | Accessorial device for the ichroma™ system | i-Chamber provides precise temperature conditions for warming and/or incubating the test cartridges as required for the ichroma™ test(s) being performed. i-Chamber is thus intended to be used for precluding any error in ichroma™ test results which may be attributed to environmental conditions like temperature. i-Chamber has been designed for incubating ichroma™ Test Cartridges only. | 29.01.10.01 | Others |
| 2. | CFPC-114 | ichroma™ COVID-19 Ab | in vitro diagnostic device for Coronavirus | ichroma™ COVID-19 Ab is a fluorescence Immunoassay (FIA) for the qualitative determination of IgG/IgM antibodies against 'Novel Coronavirus' in human whole blood/serum/plasma. It is helpful as an aid in the screening of early mild, asymptomatic or acute patients for identification of 'Novel Coronavirus (eg, SARS, 2019-nCoV)' infection with high sensitivity. For in vitro diagnostic use only. | 15.04.80.19 | Others |
| 3. | SMFP-72 | AFIAS COVID-19 Ab | in vitro diagnostic device for Coronavirus | AFIAS COVID-19 Ab is a fluorescence Immunoassay (FIA) for the qualitative determination of IgG/IgM antibodies against 'Novel Coronavirus' in human whole blood/serum/plasma. It is helpful as an aid in the screening of early mild, asymptomatic or acute patients for identification of 'Novel Coronavirus (eg, SARS, 2019-nCoV)' infection with high sensitivity. For in vitro diagnostic use only. | 15.04.80.19 | Others |
| 4. | UFPK-4 | ExAmplar COVID-19 real-time PCR kit (L) | in vitro diagnostic device for Coronavirus | ExAmplar COVID-19 real-time PCR kit (L) is a kit for the in vitro qualitative detection of 2019 novel coronavirus (SARS-CoV-2) in respiratory specimens and sera. 2 sets of primer and probe are designed for the universal detection of betacoronaviruses(E gene) and for specific detection of SARS-CoV-2(RdRp gene) responsible for COVID-19. | 15.04.40.19 | Others |
| 5. | EZPC-30 | EZ POC AFP | in vitro diagnostic device for AFP | EZ POC AFP is a fluorescence Immunoassay (FIA) for the quantitative determination of Alpha Feto Protein (AFP) in human whole blood/serum/plasma. It is useful as an aid in management and monitoring of primary hepatocellular carcinoma and non seminomatous testicular cancer. For in vitro diagnostic use only. | 12.03.90.01 | Others |
| 6. | EZPC-25 | EZ POC Anti-CCP Plus | in vitro diagnostic device for Anti-CCP | EZ POC Anti-CCP Plus is a fluorescence Immunoassay (FIA) for the qualitative or semi-quantitative determination of human IgG autoantibodies to cyclic citrullinated peptides (CCP) in human whole blood/serum/plasma. It is useful as an aid in the diagnosis of rheumatoid arthritis (RA) in combination with other clinical and laboratory findings. For in vitro diagnostic use only. | 12.11.01.11 | Others |
| 7. | EZPC-24 | EZ POC ASO | in vitro diagnostic device for ASO | EZ POC ASO is a fluorescence Immunoassay (FIA) for the quantitative determination of Anti Streptolysin O (ASO) in human serum/plasma. It is useful as an aid in management and monitoring of scarlet fever, rheumatic fever and post infectious glomerulonephritis along with several other conditions. For in vitro diagnostic use only. | 12.11.01.05 | Others |

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|-----|---------|-----------------------|--|---|-------------|--------|
| 8. | EZPC-49 | EZ POC Calprotectin | in vitro diagnostic device for Calprotectin | EZ POC Calprotectin is a fluorescence Immunoassay (FIA) for quantitative determination of Calprotectin (MRP8/14; S100A8/S100A9) in human feces. It is useful as an aid in management and monitoring of the reflex gastrointestinal inflammation caused by several pathologies (inflammatory bowel disease, colorectal cancer and some enteropathies). For in vitro diagnostic use only. | 12.01.90.10 | Others |
| 9. | EZPC-32 | EZ POC Cardiac Triple | in vitro diagnostic device for Tn-I, CK-MB and Myoglobin | EZ POC Cardiac Triple is a Fluorescence Immunoassay (FIA) for the quantitative determination of cardiac troponin-I (Tn-I), Creatine kinase (CK-MB) and Myoglobin in human whole blood/serum/plasma. It is useful as an aid in management and monitoring of acute myocardial infarction (AMI) and acute coronary syndrome (ACS). For in vitro diagnostic use only. | 12.30.01.90 | Others |
| 10. | EZPC-29 | EZ POC CEA | in vitro diagnostic device for CEA | EZ POC CEA is a fluorescence Immunoassay (FIA) for the quantitative determination of CEA in human serum/plasma. It is useful as an aid in management and monitoring of cancer patients. For in vitro diagnostic use only. | 12.03.01.31 | Others |
| 11. | EZPC-22 | EZ POC CK-MB | in vitro diagnostic device for CK-MB | EZ POC CK-MB is a fluorescence Immunoassay (FIA) for the quantitative determination of Creatine Kinase Isoenzyme-MB (CK-MB) in human whole blood/serum/plasma. It is useful as an aid in management and monitoring of acute myocardial infarction (AMI) and acute coronary syndrome (ACS). For in vitro diagnostic use only. | 12.13.01.02 | Others |
| 12. | EZPC-28 | EZ POC Cortisol | in vitro diagnostic device for Cortisol | EZ POC Cortisol is a fluorescence Immunoassay (FIA) for the quantitative determination of Cortisol in human whole blood/serum/ plasma. It is useful as an aid in management and monitoring of concentration of cortisol. For in vitro diagnostic use only. | 12.06.02.04 | Others |
| 13. | EZPC-33 | EZ POC Cystatin C | in vitro diagnostic device for Cystatin C | EZ POC Cystatin C is a fluorescence Immunoassay (FIA) for the quantitative determination of cystatin C in human serum/plasma. It is useful as an aid in management and monitoring of renal disease. For in vitro diagnostic use only. | 12.01.90.09 | Others |
| 14. | EZPC-21 | EZ POC D-Dimer | in vitro diagnostic device for D-Dimer | EZ POC D-Dimer is a fluorescence Immunoassay (FIA) for the quantitative determination of D-Dimer in human whole blood / plasma. It is useful as an aid in management and monitoring of post therapeutic evaluation of thromboembolic disease patients. For in vitro diagnostic use only. | 13.02.05.03 | Others |
| 15. | EZPC-15 | EZ POC Dengue IgG/IgM | in vitro diagnostic device for Dengue IgG/IgM | EZ POC Dengue IgG/IgM is a fluorescence Immunoassay (FIA) for the qualitative determination of IgG/IgM antibodies against dengue virus in human whole blood/serum/plasma. It is useful as an aid in screening of Dengue virus infection. For in vitro diagnostic use only. | 15.04.80.11 | Others |
| 16. | EZPC-16 | EZ POC Dengue NS1 Ag | in vitro diagnostic device for Dengue NS1 Ag | EZ POC Dengue NS1 Ag is a fluorescence Immunoassay (FIA) for the qualitative determination of NS1 Antigen in human whole blood/serum/plasma during dengue virus infection. It is useful as an aid in screening of early Dengue virus infection. For in vitro diagnostic use only. | 15.04.80.11 | Others |
| 17. | EZPC-18 | EZ POC Ferritin | in vitro diagnostic device for Ferritin | EZ POC Ferritin is a fluorescence Immunoassay (FIA) for the quantitative determination of Ferritin in human serum/plasma. It is useful as an aid in quantifies human ferritin. For in vitro diagnostic use only. | 12.07.01.02 | Others |

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| 18. | EZPC-19 | EZ POC FSH | in vitro diagnostic device for FSH | EZ POC FSH is a fluorescence Immunoassay (FIA) for the quantitative determination of follicle stimulating hormone (FSH) in human serum/plasma. It is useful as an aid in management and monitoring of concentration of FSH. For in vitro diagnostic use only. | 12.05.01.04 | Others |
| 19. | EZPC-39 | EZ POC H.pylori SA | in vitro diagnostic device for H.pylori | EZ POC H. pylori SA (H. pylori Stool Antigen) is a fluorescence Immunoassay (FIA) for the qualitative determination of H. pylori antigen in human feces. It is useful as an aid in the diagnosis of H. pylori infection and to demonstrate loss of H. pylori antigen following treatment. For in vitro diagnostic use only | 15.01.04.01 | Others |
| 20. | EZPC-26 | EZ POC hsCRP | in vitro diagnostic device for CRP | EZ POC hsCRP is a fluorescence Immunoassay (FIA) for the quantitative determination of CRP in human whole blood/serum/plasma. It is useful as an aid in management and monitoring of risk of cardiovascular diseases. For in vitro diagnostic use only. | 12.13.01.10 | Others |
| 21. | EZPC-35 | EZ POC iFOB Neo | in vitro diagnostic device for iFOB | EZ POC iFOB Neo is a fluorescence Immunoassay (FIA) for the quantitative determination of hemoglobin in human feces. It is useful as an aid in management and monitoring of colorectal cancer. For in vitro diagnostic use only. | 12.03.90.04 | Others |
| 22. | EZPC-17 | EZ POC LH | in vitro diagnostic device for LH | EZ POC LH is a fluorescence Immunoassay (FIA) for the quantitative determination of Luteinizing hormone (LH) in human serum/plasma. It is useful as an aid in management and monitoring of determination of evaluating fertility issues, function of reproductive organs (ovaries or testicles), or detection of the ovulation. For in vitro diagnostic use only. | 12.05.01.05 | Others |
| 23. | EZPC-14 | EZ POC Microalbumin | in vitro diagnostic device for Microalbumin | EZ POC Microalbumin is a fluorescence Immunoassay (FIA) for the quantitative determination of Microalbumin in human urine. It is useful as an aid in management and monitoring of determination of kidney damage from diabetes. For in vitro diagnostic use only. | 12.01.03.01 | Others |
| 24. | EZPC-31 | EZ POC Myoglobin | in vitro diagnostic device for Myoglobin | EZ POC Myoglobin is a fluorescence Immunoassay (FIA) for the quantitative determination of Myoglobin in human whole blood/serum/plasma. It is useful as an aid in management and monitoring of acute myocardial infarction (AMI). For in vitro diagnostic use only. | 12.13.01.05 | Others |
| 25. | EZPC-23 | EZ POC NT-proBNP | in vitro diagnostic device for NT-proBNP | EZ POC NT-proBNP is a fluorescence Immunoassay (FIA) for the quantitative determination of NT-proBNP in human whole blood/ serum/plasma. It is useful as an aid in the diagnosis of persons suspected of having congestive heart failure. For in vitro diagnostic use only. | 12.13.01.01 | Others |
| 26. | EZPC-12 | EZ POC Progesterone | in vitro diagnostic device for Progesterone | EZ POC Progesterone is a fluorescence Immunoassay (FIA) for the quantitative determination of progesterone in human serum/plasma. It is useful as an aid in management and monitoring of the cause of infertility, track ovulation, diagnose an ectopic or failing pregnancy, monitor the health of a pregnancy. For in vitro diagnostic use only. | 12.05.01.06 | Others |
| 27. | EZPC-27 | EZ POC Testosterone | in vitro diagnostic device for Testosterone | EZ POC Testosterone is a fluorescence Immunoassay (FIA) for the quantitative determination of Testosterone in human serum/plasma. It is useful as an aid in management and monitoring of androgen level. For in vitro diagnostic use only. | 12.05.01.10 | Others |

* Annex A is part of the Agreement.

** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (IVD 98/79/EC).

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