



Medicines & Healthcare products
Regulatory Agency



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mhra.gov.uk

Certificate number: **2019100102174237/9**

Order date: **07/10/2019**

CFS Expiry date: **07/10/2024**

Medicines and Healthcare products Regulatory Agency

On behalf of the Secretary of State for Health and Social Care

CERTIFICATE OF FREE SALE FOR EXPORTATION OF MEDICAL PRODUCTS

It is hereby certified that, on the basis of information provided, the products named below and detailed in the attached schedule (if applicable), which are manufactured by: Legal Manufacturer: **Prestige Diagnostics U.K. Ltd**, 40 Ballymena Business Centre, Galgorm, Ballymena, County Antrim, BT42 1FL, United Kingdom, have been affixed with the CE mark under In-Vitro Diagnostic Medical Devices Directive 98/79/EC as transposed into UK legislation (UK Medical Devices Regulations 2002 S.I. No. 618, as amended) and therefore may be freely sold in all member states of the European Economic Area including the United Kingdom.

Please see attached schedule

Where appropriate, Certificates of Free Sale are issued as a service to UK exporters. A Certificate of Free Sale should not be taken as a Government endorsement of any product that is referred to on the certificate.

Yours sincerely,

Lewis Kennedy

Certificate of Free Sale Administration Team
Signed on Behalf of MHRA





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| 32 | Group A Streptococcus antigen Rapid Test Device | Group A Streptococcus antigen immunochromatographic test |
| 33 | Group B Streptococcus antigen Rapid Test Device | Group B Streptococcus antigen immunochromatographic test |
| 34 | Serological albumin | Serological albumin |
| 35 | Fatty acid binding protein device | Fatty acid binding protein enzyme immunoassay |
| 36 | Proteus stained antigen suspension | Febrile antigens |
| 37 | 6-Acetyl morphine enzyme immunoassay (EIA) | 6-Acetyl morphine IVD, kit, enzyme immunoassay (EIA) |
| 38 | ABO multiple blood grouping agglutination | ABO multiple blood grouping IVD, kit, agglutination |
| 39 | Toxoplasma gondii immunoglobulin G (IgG) ELISA | Toxoplasma gondii immunoglobulin G (IgG) |
| 40 | Toxoplasma gondii immunoglobulin G (IgG) Rapid Test Device | Toxoplasma gondii immunoglobulin G (IgG) |
| 41 | Toxoplasma gondii immunoglobulin M (IgM) ELISA | Toxoplasma gondii immunoglobulin M (IgM) |
| 42 | Toxoplasma gondii immunoglobulin M (IgM) Rapid Test Device | Toxoplasma gondii immunoglobulin M (IgM) |
| 43 | Anti Streptolysin O Calibrator | Group A Streptococcus streptolysin O antibody IVD, calibrator |
| 44 | Anti streptolysin O Control | Group A Streptococcus streptolysin O antibody IVD, control |
| 45 | Group A Streptococcus streptolysin O antibody Reagent | Group A Streptococcus streptolysin O antibody IVD, reagent |
| 46 | Anti Streptolysin O Visilatex Reagent | Streptococcus streptolysin O antibody IVD, kit, agglutination, rapid |
| 47 | Calcium Arsenazo Reagent | Calcium (Ca ²⁺) IVD, reagent |
| 48 | Calcium OCPC Reagent | Calcium (Ca ²⁺) IVD, reagent |
| 49 | Calcium chloride Coagulation Reagent | Calcium chloride coagulation reagent |
| 50 | Autotron 120 Clinical Chemistry Analyser | Multichannel clinical chemistry analyser |





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| 71 | Total Prostate Specific Antigen (PSA) Elisa | Total prostate specific antigen (PSA) IVD, kit, enzyme immunoassay (EIA) |
| 72 | Lactate Dehydrogenase (LDH) Reagent | Total lactate dehydrogenase (LDH) IVD, reagent |
| 73 | Amylase Reagent | Total amylase IVD, reagent |
| 74 | Haemoglobin (totHb) Reagent | Total haemoglobin (totHb) IVD, reagent |
| 75 | Total creatine kinase (CK) IVD, reagent | Creatine kinase (CK) Reagent |
| 76 | Cholesterol Reagent | Total cholesterol lipid IVD, reagent |
| 77 | Total Aspartate Aminotransferase (AST) Reagent | Total aspartate aminotransferase (AST) IVD, reagent |
| 78 | Alkaline phosphatase (ALP) Reagent | Total alkaline phosphatase (ALP) IVD, reagent |
| 79 | Thyroid stimulating hormone (TSH) Elisa | Thyroid stimulating hormone (TSH) IVD, kit, enzyme immunoassay (EIA) |
| 80 | Thrombin time (TT) Reagent | Thrombin time (TT) IVD, reagent |
| 81 | Sodium Reagent | Sodium (Na ⁺) IVD, reagent |
| 82 | Rubella Virus Immunoglobulin M (IgM) Antibody Enzyme Immunoassay (EIA) | Rubella virus immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA) |
| 83 | Rubella Virus Immunoglobulin G (IgG) Antibody Enzyme immunoassay (EIA) | Rubella virus immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA) |
| 84 | Rotavirus Antigen Rapid Test Device | Rotavirus antigen IVD, kit, immunochromatographic test (ICT), rapid |
| 85 | Activated partial thromboplastin time (APTT) Reagent | Activated partial thromboplastin time (APTT) IVD, Reagent |
| 86 | Rheumatoid Factor Nephelometry / Turbidimetry | Rheumatoid factor IVD, kit, nephelometry/turbidimetry |
| 87 | Prothrombin time Clotting Reagent | Prothrombin time (PT) IVD, kit, clotting |
| 88 | Rheumatoid Factor Visilatex Reagent | Rheumatoid factor IVD, kit, agglutination |
| 89 | Rheumatoid Factor Control | Rheumatoid factor IVD, control |
| 90 | Rheumatoid Factor Calibrator | Rheumatoid factor IVD, calibrator |





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| 157 | Cytomegalovirus (CMV) Immunoglobulin M (IgM) ELISA | Cytomegalovirus (CMV) Immunoglobulin M (IgM) Antibody IVD, Kit, Enzyme Immunoassay (EIA) |
| 158 | Cytomegalovirus (CMV) Immunoglobulin G (IgG) ELISA | Cytomegalovirus (CMV) Immunoglobulin G (IgG) Antibody IVD, Kit, Enzyme Immunoassay (EIA) |
| 159 | Creatine Kinase Myocardial Isoenzyme (CKMB) Rapid Test Device | Creatine Kinase Myocardial Isoenzyme (CKMB) IVD, Kit, Immunochromatographic Test (ICT) Rapid Test Device |
| 160 | Creatine Kinase (CKNAC) Reagent | Creatine Kinase (CK) Multiple Isoenzyme IVD, Reagent |
| 161 | C-Reactive Protein (CRP) Nephelometry / Turbidimetry | C-Reactive Protein (CRP) IVD, Kit, Nephelometry / Turbidimetry |
| 162 | C-Reactive protein (CRP) Visilatex Reagent | C-Reactive Protein (CRP) IVD, Kit, Agglutination, Rapid |
| 163 | C-Reactive Protein (CRP) Calibrator | C-reactive Protein (CRP) IVD, Calibrator |
| 164 | Copper Reagent | Copper IVD, Reagent |
| 165 | Cocaine / Cocaine Metabolite Rapid Test Device | Cocaine / Cocaine Metabolite IVD, Kit, Immunochromatographic Test (ICT), Rapid |
| 166 | Coagulation Factor IIa Thrombin Time Reagent | Coagulation Factor IIa Thrombin) IVD, Reagent |
| 167 | Coagulation Factor II (Prothrombin Time Reagent) | Coagulation Factor II (Prothrombin) IVD, Reagent |
| 168 | Turboclot | Coagulation Analyser IVD, Laboratory, Semi-Automated |
| 169 | Turbolyte | Coagulation analyser IVD, laboratory, semi-automated |
| 170 | Chloride (Cl-) Reagent | Chloride (Cl-) IVD, reagent |
| 171 | Cholinesterase Reagent | Cholinesterase Dibucaine Number (percentage inhibition) IVD, Reagent |
| 172 | Carcinoembryonic Antigen (CEA) ELISA | Carcinoembryonic Antigen (CEA) IVD, Kit, Enzyme Immunoassay (EIA) |





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| 189 | Creatine kinase myocardial isoenzyme (CKMB) Reagent | Creatine kinase myocardial isoenzyme (CKMB) IVD, reagent |
| 190 | Creatine kinase myocardial isoenzyme (CKMB) Reagent Dry | Creatine kinase myocardial isoenzyme (CKMB) Reagent |
| 191 | Creatine kinase (CK) Control | Creatine kinase (CK) multiple isoenzyme Control |
| 192 | Ferritin ELISA | Ferritin IVD, kit, enzyme immunoassay (EIA) |
| 193 | Glucose Reagent | Glucose Reagent Single Liquid |
| 194 | Glucose Reagent Lyophilised | Glucose Reagent Lyo |
| 195 | Brucella abortus Agglutination Reagent | Brucella species culture isolate antigen Agglutination Reagent |
| 196 | Brucella melitensis Agglutination Reagent | Brucella species culture isolate antigen Agglutination Reagent |
| 197 | Urea UV Reagent | Urea IVD, reagent |
| 198 | Urea Colour Reagent | Urea IVD, reagent |
| 199 | Total Bilirubin Reagent | Total/conjugated (direct) bilirubin Reagent |
| 200 | Direct Bilirubin Reagent | Total/conjugated (direct) bilirubin Reagent |
| 201 | Total Bilirubin / Direct Bilirubin Combo | Total/conjugated (direct) bilirubin Reagent |
| 202 | Urine Strips | Multiple urine analyte IVD, kit, colorimetric dipstick, rapid |
| 203 | Treponema pallidum reagin antibody kit, agglutination | Treponema pallidum reagin antibody IVD, kit, agglutination |
| 204 | RPR Reagent | Treponema pallidum reagin antibody IVD, kit, agglutination |
| 205 | Lactate Dehydrogenase (LDH) (L - P) Reagent | Total lactate dehydrogenase (LDH) IVD, reagent |
| 206 | Lactate Dehydrogenase (LDH) (P - L) Reagent | Total lactate dehydrogenase (LDH) IVD, reagent |
| 207 | Febrile Antigen Reagent | Multiple Salmonella species antigen IVD, reagent |
| 208 | Febrile Positive Control | Multiple febrile infection-associated bacteria antigen IVD, control |
| 209 | Febrile Negative Control | Multiple febrile infection-associated bacteria antigen IVD, control |

