Medicines & Healthcare products
Regulatory Agency

MHRA

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Medimap Ltd
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Thurston
IP31 3RT
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12 August 2021

Dear

We are pleased to confirm that the application to register or update an existing registration for the following manufacturer, which you submitted on **12 August 2021** has been reviewed:

Application reference:

Manufacturer organisation:
Address:

Manufacturer registration status: **Registered**

Device(s):

GMDN term	Status	MHRA comment
Follicle stimulating hormone (FSH) IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Vaginal pH screening IVD, kit, colorimetric dipstick, self-testing	Registered	
Faecal occult blood IVD, kit, immunochromatographic test (ICT), self-testing	Registered	
Anti-Mullerian hormone (AMH) IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Helicobacter pylori immunoglobulin G (IgG) antibody IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Candida albicans antigen IVD, reagent	Registered	
Dengue virus NS1 antigen IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Neisseria gonorrhoeae antigen IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Legionella pneumophila antigen IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Epstein-Barr virus (EBV) heterophile antibody IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Multiple Plasmodium species antigen IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Herpes simplex virus 1 & 2 (HSV1 & 2) immunoglobulin G (IgG)/IgM antibody IVD, reagent	Registered	

GMDN term	Status	MHRA comment
Streptococcus pneumoniae antigen IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Beta-haemolytic Group A Streptococcus antigen IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Treponema pallidum immunoglobulin G (IgG)/IgM antibody IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Mycobacterium tuberculosis complex species antigen IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Trichomonas vaginalis antigen IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Salmonella typhi antigen IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Cancer antigen 125 (CA125) IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Cancer antigen 15-3 (CA15-3) IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Cancer antigen 19-9 (CA19-9) IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Alpha-fetoprotein (AFP) IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Carcinoembryonic antigen (CEA) IVD, kit, immunochromatographic test (ICT)	Registered	
D-dimer IVD, kit, immunochromatographic test (ICT), rapid	Registered	

GMDN term	Status	MHRA comment
Multiple cardiac marker IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Thyroid stimulating hormone (TSH) IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Calprotectin IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Allergen-specific immunoglobulin E (IgE) antibody IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Multiple alcohol IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Amphetamine-specific IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Benzodiazepine group IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Cocaine/cocaine metabolite IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Cotinine IVD, kit, immunochromatographic test (ICT), rapid	Registered	
2-ethylidine-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) IVD, reagent	Registered	
Ethyl glucuronide (EtG) IVD, reagent	Registered	
Fentanyl IVD, kit, immunochromatographic test (ICT), rapid	Registered	

GMDN term	Status	MHRA comment
Neurontin (gabapentin) IVD, reagent	Registered	
Gamma-hydroxybutyrate (GHB) IVD, reagent	Registered	
Ketamine/ketamine metabolite IVD, reagent	Registered	
Lysergic acid diethylamide (LSD)/LSD metabolite IVD, kit, immunochromatographic test (ICT), rapid	Registered	
6-Acetyl morphine IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Amphetamine/methamphetamine group IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Methamphetamine-specific IVD, kit, immunochromatographic test (ICT) assay, rapid	Registered	
Morphine/morphine metabolite IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Pregabalin IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Cannabinoid IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Tramadol IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Human astrovirus antigen IVD, kit, immunochromatographic test (ICT), rapid	Registered	

GMDN term	Status	MHRA comment
Multiple Campylobacter species antigen IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Beta-haemolytic Group B Streptococcus antigen IVD, kit, immunochromatographic test (ICT), rapid	Registered	
C-reactive protein (CRP) IVD, kit, immunochromatographic test (ICT)	Registered	
Glycated haemoglobin (HbA1c) IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Lactoferrin IVD, kit, immunochromatographic test (ICT)	Registered	
Tricyclic antidepressant IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Methadone IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Oxycodone IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Phencyclidine (PCP) IVD, kit, immunochromatographic test (ICT)	Registered	
Propoxyphene/propoxyphene metabolite IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Total human chorionic gonadotropin (HCG) IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Urine test strip colour chart IVD	Registered	

GMDN term	Status	MHRA comment
Multiple urine analyte IVD, kit, colorimetric dipstick, rapid	Registered	
Multiple drugs of abuse IVD, kit, immunochromatographic test (ICT), rapid	Registered	

Please note this letter does not represent any form of accreditation, certification or approval by the UK Competent Authority.

If you stop placing devices on the market or if you are not complying with the Regulations, you should inform us so that we can amend our records. You should be aware that it is an offence to place on the market UKCA or CE marked devices that do not comply with the regulations.

Please inform us of the following chargeable changes:

1. **company/organisation information e.g. name and address**
2. **additional devices (GMDN code or term)**

Please also use the Devices Online Registration Database (DORS) to tell us of the following changes e.g. removal/ discontinuation of a device (GMDN) or product from your registration record, change of contact person, telephone number and/or email address, for which payment of our statutory fee does not apply.

Please note that the name and address of manufacturer, UK Responsible Person or Authorised Representative (Northern Ireland only) and devices that have been registered will be published on our Public Access Registration Database (PARD).

The account number for your company/organisation is

Yours sincerely,

Ngozi Onyeukwu
Device registrations service
Devices division
MHRA