Medicines & Healthcare products Regulatory Agency

MHRA

Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

+44 (0) 20 3080 6000
gov.uk/mhra

Medimap Ltd
2 The Drift
Suffolk
Thurston
IP31 3RT
United Kingdom

28 July 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 **15 July 2021** has been reviewed:

Application reference:

Manufacturer organisation:
Address:

Manufacturer registration status: **Registered**

Device(s):

GMDN term	Status	MHRA comment
SARS-CoV-2 antigen IVD, kit, immunochromatographic test (ICT), self-testing	Registered	
Sperm concentration indicator IVD, kit, immunochromatographic test (ICT), self-testing	Registered	
Helicobacter pylori antigen IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Ferritin IVD, kit, immunochromatographic test (ICT), self-testing	Registered	
Thyroid stimulating hormone (TSH) IVD, kit, immunochromatographic test (ICT), self-testing	Registered	
Multiple form 25-hydroxy vitamin D IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Faecal occult blood IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Chlamydia pneumoniae antigen IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Total prostate specific antigen (tPSA) IVD, kit, immunochromatographic test (ICT), rapid	Registered	
Luteinizing hormone (LH) 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