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**

**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, | Registered | |
| 65665 - Faecal occult blood IVD, | Registered | |
| Thyroid stimulating hormone (TSH) IVD, kit, immunochromatographic test (ICT), rapid | Registered | |
| Multiple alcohol IVD | 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 | |

| GMDN term | Status | MHRA comment |
| --- | --- | --- |
| Ketamine/ketamine metabolite IVD, reagent | Registered | |
| Amphetamine/methamphetamine group IVD | Registered | |
| Methamphetamine-specific IVD | Registered | |
| Morphine/morphine metabolite IVD | Registered | |
| Pregabalin IVD | Registered | |
| Cannabinoid IVD | | |
| Tramadol IVD | Registered | |
| Methadone IVD | Registered | |
| Oxycodone IVD | Registered | |
| Total human chorionic gonadotropin (HCG) IVD | Registered | |
| Urine test strip colour chart IVD | Registered | |

| GMDN term | Status | MHRA comment |
|---|---|---|
| Multiple drugs of abuse IVD | 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