Medicines & Healthcare products
Regulatory Agency

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Wellkang Ltd
Enterprise Hub, NW Business Complex
1 Beraghmore Road
Derry, Northern Ireland
BT48 8SE
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28 April 2022

Dear **Yas Godoy**

We are pleased to confirm that the application to register or update an existing registration for the following manufacturer, which you submitted on **28 April 2022** has been reviewed:

Application reference: **2022042801260525**

Manufacturer organisation: **NewScen Coast Bio-Pharmaceutical Co., Ltd.**
Address:
No. 65, 6th Street,
Tianjin TEDA,
Tianjin
300457
China

Manufacturer registration status: **Registered**

Device(s):

GMDN Code & Term	Status	Comment
58305 - Procalcitonin (PCT) IVD, kit, immunochromatographic test (ICT), rapid	Registered	
58395 - C-reactive protein (CRP) IVD, kit, immunochromatographic test (ICT)	Registered	
63981 - Alpha-fetoprotein (AFP) IVD, kit, immunochromatographic test (ICT), rapid	Registered	
54617 - Carcinoembryonic antigen (CEA) IVD, kit, immunochromatographic test (ICT)	Registered	
61295 - Multiple cardiac marker IVD, kit, immunochromatographic test (ICT), rapid	Registered	
47343 - D-dimer IVD, kit, immunochromatographic test (ICT), rapid	Registered	
60471 - Microalbumin IVD, kit, immunochromatographic test (ICT), rapid	Registered	
65274 - Thyroid stimulating hormone (TSH) IVD, kit, immunochromatographic test (ICT), rapid	Registered	
54212 - Total human chorionic gonadotropin (HCG) IVD, reagent	Registered	
65974 - Multiple anti-neutrophil cytoplasmic antibody/glomerular basement membrane antibody IVD, kit, fluorescent immunoassay	Registered	
65841 - Follicle stimulating hormone (FSH) IVD, kit, immunochromatographic test (ICT), self-testing	Registered	
63167 - Ferritin IVD, kit, immunochromatographic test (ICT), self-testing	Registered	

GMDN Code & Term	Status	Comment
65665 - Faecal occult blood IVD, kit, immunochromatographic test (ICT), self-testing	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). In vitro diagnostic medical devices registered as undergoing performance evaluation study are not published on this database.

The account number for your company/organisation is **0000010590.**

Please do not respond directly to this email address. The originating email account is not monitored.

Yours sincerely,

Ngozi Onyeukwu
Device registrations service
Devices division
Medicines and Healthcare products Regulatory Agency