Medicines & Healthcare products Regulatory Agency

MHRA

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27 November 2020

Dear **Xueli WEI**

We are pleased to confirm that the application to register or update an existing registration for the following manufacturer, which you submitted on **02 November 2020** has been reviewed:

Application reference: **2020110201186582**

Manufacturer organisation: **Xiamen Boson Biotech Co., Ltd.**
Address:
90-94 Tianfeng Road, Jimei North Industrial Park
Fujian
Xiamen
361021
China

Manufacturer registration status: **Registered**

Device(s):

GMDN term	Status	MHRA comment
64756 - SARS-CoV-2 immunoglobulin G (IgG)/ IgM antibody IVD, kit, immunochromatographic test (ICT), rapid	Registered	
64787 - SARS-CoV-2 antigen 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 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 manufacturers and authorised representatives and their devices that have been registered will be published on our Public Access Registration Database (PARD). This applies to non-in vitro diagnostic devices only.

The account number for your company/organisation is **0000010786.**

Yours sincerely,

Ngozi Onyeukwu
Device registrations service
Devices division
MHRA