

DG Post/ Health Products Division / Medical Devices Entity

Contact : Nadya Tavajjoh

Tel. : 02/ 528 40 40  
e-mail: IVD@afmps.be

Qarad b.v.b.a.  
Cipalstraat 3  
2440 Geel

Your letter from	Our reference	Date	Indicator
11/03/2020	FAGG/2020/XDC/NAT/90054		

**Subject :** notification by the manufacturer or his authorized representative concerning the placing on the market of in vitro diagnostic medical devices, in accordance with Article 5 of the Royal Decree of November 14, 2001 on medical devices for in vitro diagnostics. This Royal Decree of November 14, 2001 is a transposition of the European Directive 98/79/EC on in vitro diagnostic medical devices.

Dear Madam, dear Sir,

I acknowledge receipt of your notification of placing on the market the in vitro diagnostic medical devices described in the appendix.

Your notification has been registered on 31/03/2020.

This acknowledgment of receipt does not in any way constitute an endorsement of the qualification and classification of the relevant in vitro diagnostic medical device or of its conformity with the essential requirements of Annex I of the Royal Decree of November 14, 2001 on medical devices for in vitro diagnostics..

Any changes to the data submitted in this notification must be reported within 30 days to the Federal Agency for Medicines and Health Products.

Please accept, Sir, the expression of my distinguished sentiments,

The Chief Executive Officer

Xavier De Cuyper

This document is a translation of the official and signed versions in Dutch or French

## Product list

### IVD for professional use :

<b>IVD</b>	<b>Registration number</b>	<b>GIVD code</b>
Wantai SARS-CoV-2 Ab ELISA (REF: WS-1096)	BE-CA01/1-90054-00002-IVD	15.04.80.19
Wantai SARS-CoV-2 IgM ELISA (REF: WS-1196)	BE-CA01/1-90054-00003-IVD	15.04.80.19
Wantai SARS-CoV-2 Ab Rapid Test (REF: WJ-2701, WJ-2710, WJ-2750)	BE-CA01/1-90054-00004-IVD	15.04.80.19

#### Manufacturer

Beijing Wantai Biological Pharmacy  
Enterprise Co., Ltd.  
No. 31 Kexueyuan Road, Changping  
District  
102206 Beijing  
China

#### Authorized representative

Qarad b.v.b.a.  
Cipalstraat 3  
2440 Geel  
Belgium

This document is a translation of the official and signed versions in Dutch or French