federal agency for medicines and health products
Avenue Galilée - Galileelaan 5/03
1210 BRUSSELS
www.afmps.be

DG Post/ Health Products Division / Medical Devices Entity

Contact 5.1.2e

Tel. : 02/ 528 40 40
e-mail: 5.1.2e@afmps.be

Qarad BV
Cipalstraat 3
2440 Geel

Your letter from	Our reference	Date	Indicator
21/01/2021	5.1.1c		

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 24/02/2021.

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,

5.1.2e

5.1.2e
5.1.2e
5.1.2e

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

Product list

IVD for professional use :

IVD	Registration number	GMDN code
Influenza/2019-nCoV Antigen Combo Test - REF: W630P0002, W630P0003, W630P0004, W630P0005, W630P0006, W630P0007, W630P0008, W630P0009, W630P0010, W630P0011	5.1.1c	
2019-nCoV Antigen Saliva/Sputum Test - REF: W633P0001, W633P0002, W633P0003, W633P0004, W633P0005, W633P0006		

Manufacturer

5.1.2a

Authorized representative

Qarad BV
Cipalstraat 3
2440 Geel
Belgium

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