

DG Post/ Health Products Division / Medical Devices Entity

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Qarad BV

Cipalstraat 3

2440 Geel

| Your letter from | Our reference | Date | Indicator |
|------------------|-------------------------|------|-----------|
| 15/02/2021 | FAGG/2021/XDC/NAT/90005 | | |

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 16/03/2021.

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,

The Chief Executive Officer

Xavier De Cuyper
i.o. Hugues MALONNE
Director-General DG-POST Authorization

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Product list

IVD for professional use :

| IVD | Registration number | GIVD code |
|---|----------------------------|------------------|
| Rapid SARS-CoV-2 Neutralizing Antibody Test (REF: ITP16012-TC1, ITP16012-TC25, ITP16012-TC40) | BE-CA01/1-90005-00028-IVD | 15.70.90.08 |

Manufacturer

InTec PRODUCTS, INC.

332 Xinguang Road, Xinyag Industrial

Area, Haicang

361022 Xiamen

China

Authorized representative

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2440 Geel

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