

## OF IVD NOTIFICATION

JROPEAN AUTHORIZED EPRESENTATIVE CENTER

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## Order No.: OG 0625-2021 Ref No.: BS 0714-2021

## Annex A - List of Devices

## (Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN / GIVD Code	Class
1.	NA	Coronavirus (SARS-Cov-2) Antigen Rapid sampling and detection tube(Colloidal Gold)	SARS-Cov-2 Antigen IVD, kit	COVID-19 Detection	64787	All Others
2.	NA	COVID-19 Antigen Saliva Rapid Test Kit (Colloidal Gold)	SARS-Cov-2 Antigen IVD, kit	COVID-19 Detection	64787	All Others
3.	NA	SARS-CoV-2 Neutralizing Antibody Test Kit	SARS-Cov-2 Total Antibody Neutralization IVD, kit	COVID-19 Detection	65307	All Others

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