

CERTIFICATE OF IVD NOTIFICATION

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G. ELKAYAM
CEO

Obelis s.a. - O.E.A.R.C.
Registered Address
Bld Général Wahis 53
1030 Brussels
Tel: +32 2 732 5954 - Fax: +32 2 732 6003

Mr. G. Elkayam CEO

Obelis sa



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Order No.: MQ 0343-2020

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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/EDMS Code	Class
1.	RM301	DNA/RNA Extraction Kit	A kit used to extract the Nucleic acid from virus	This kit is applicable for extracting highly pure viral nucleic acid (DNA/RNA) from samples such as blood, Serum, plasma, human nasopharyngeal swabs, sputum, broncho lavage fluid and alveolar lavage fluid.	15.90.40.01	others
2.	VNP-32YL	Automatic nucleic acids extraction instrument	The instrument for nucleic acid extraction with nucleic acid extraction kit	Instrument for extraction, purification of nucleic acid from clinical samples	26.02.10.01	others
3.	C8909C	Anti-SARS-CoV-2 Neutralizing Antibody ELISA Kit	An ELISA method based kit which qualitatively detect the neutralizing antibodies.	The SARS-CoV-2 Neutralization Antibody Detection Kit is a competitive elisa assay intended for the qualitative detection of neutralization antibodies against SARS-CoV-2 in human serum. The SARS-CoV-2 Neutralization Antibody Detection Kit is intended for use as an aid in identifying individuals with a protective immune response to SARS-CoV-2.	15.04.80.19	others

4.	C8009C	Anti-SARS-CoV-2 Neutralizing Antibody TR-FRET Kit	An TR-FRET Kit method based kit which qualitatively detect the neutralizing antibodies.	The SARS-CoV-2 Neutralization Antibody Detection Kit is a competitive elisa assay intended for the qualitative detection of neutralization antibodies against SARS-CoV-2 in human serum. The SARS-CoV-2 Neutralization Antibody Detection Kit is intended for use as an aid in identifying individuals with an protective immune response to SARS-CoV-2.	15.04.80.19	others
5.	C9602C	SARS-CoV-2 and Influenza A/B Virus Antigen Combined Detection Kit(Colloidal Gold-Based)	a combined antigen kit of Coronavirus and influenza A/B	The kit is suitable for qualitative detection of SARS-CoV-2 antigen, influenza A virus antigen and influenza B virus antigen in human nasal swab and throat swab samples.	15.30.02.49	others
6	CD502	Novel Coronavirus(SARS-CoV-2) and Influenza A/B Virus RT-qPCR Detection Kit	A RT-qPCR test kit which can detect SARS-COV-2 and influenza A/B together	This kit is a real-time RT-PCR test intended for the qualitative detection of nucleic acids from the SARS-CoV-2, influenza A and influenza B virus in nasopharyngeal/oropharyngeal swab, sputum.	15.30.02.49	others

7	CD312	2019-Novel Coronavirus (2019-nCoV) Triplex RT-qPCR Detection Kit	In Vitro Diagnostic Kit of SARS-COV-2.	This product is intended for the detection of 2019-Novel Coronavirus (2019-nCoV). The detection result of this product is only for clinical reference, and it should not be used as the only evidence for clinical diagnosis and treatment.	15.70.90.08	others
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* Annex A is part of the Agreement.

** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (IVD 98/79/EC).

Obelis s.a.

Signature:


 Obelis s.a. - O.E.A.R.C.
 Registered Address :
 Bld Général Wahis 53
 1030 Bruxelles
 Tél. +32 2 732 59 54 - Fax +32 2 732 60 63