



CERTIFICATE OF IVD NOTIFICATION

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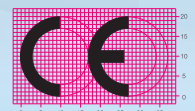
Mr. G. Elkayam CEO

Obelis sa



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Ref No.: DT 9759-2020

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.	QP019R-0100	COVID-19 RT-qPCR Detection Kit	SARS-CoV-2 nucleic acid IVD, kit, nucleic acid technique (NAT)	This kit is used for the qualitative detection of nucleic acid from SARS- CoV-2 in human respiratory tract specimens by real time PCR systems. This test is used to aid the diagnosis of COVID-19 infection.	64747	All others

** 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:**


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