



CERTIFICATE OF IVD NOTIFICATION

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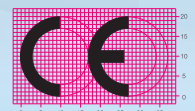
Mr. G. Elkayam CEO

Obelis sa



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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 Code	Class
1.	RED-19-01	REDx™ SARS-CoV-2 Positive Control	Unassayed SARS-CoV-2 positive control	For IVD use as unassayed positive control intended to monitor the laboratory testing performance, procedures and workflow with nucleic-acid assays that detect SARS-CoV-2.	64748	All others
2.	RED-99-M3	REDx™ SARS-CoV-2 Negative Control	SARS-CoV-2 negative control	For IVD use as unassayed negative control intended to monitor the laboratory testing performance, procedures and workflow with nucleic-acid assays that detect SARS-CoV-2.	64748	All others
3.	RED-S-19-01	REDx™FLOQ™ SARS-CoV-2 Swab Positive Control	Unassayed SARS-CoV-2 positive swab control	For IVD use as unassayed positive swab control intended to monitor the laboratory testing performance, procedures and workflow with nucleic-acid assays that detect SARS-CoV-2.	64748	All others
4.	RED-S-99-M4	REDx™FLOQ™ SARS-CoV-2 Swab Negative Control	Unassayed SARS-CoV-2 negative swab control	For IVD use as unassayed negative swab control intended to monitor the laboratory testing performance, procedures and workflow with nucleic-acid assays that detect SARS-CoV-2.	64748	All others

* 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: _____

Stamp: _____

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