



CERTIFICATE OF IVD NOTIFICATION

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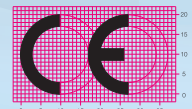
Mr. G. Elkayam CEO

Obelis sa



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V3 - ID: 00454716 - 22/02/2019



Order No.: DK 9861-2020N
Ref No.: BS 0014-2020

Annex A - List of Devices

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

#	Catalogue reference number/Model	Commercial Name	Generic Device Term	Short description and intended use	GMDN/EDMS Code	Class
1.	C2420/LabTurbo 24 Compact System; C4820/LabTurbo 48 Compact System	LabTurbo Automated Nucleic Acid Purification System	NA Extraction Hardware + accessories + consumables + software	Full automation for nucleic acid extraction	26.02.10.01	All Others
2.	24C-LGD480-220; 24C-LGD480-300; 24C-LGD480-500; 24C-LGD480-1000; 24C-LGD480-2000; LGD480-220; LGD480-300; LGD480-500; LGD480-1000; LGD480-2000; 45X-LGD480-2000	LabTurbo DNA Mini Kit	Reagents for DNA and/or RNA extraction and preparation: bacteria and/or virus	Kit for genomic DNA extraction	15.90.40.01	All Others
3.	24C-LTR480-500; 24C-LTR480-1000; LTR480-500; LTR480-1000	LabTurbo RNA Mini Kit	Reagents for DNA and/or RNA extraction and preparation: bacteria and/or virus	Kit for total RNA extraction	15.90.40.01	All Others
4.	24C-LVN480-220; 24C-LVN480-300; 24C-LVN480-500; 24C-LVN480-1000; LVN480-220; LVN480-300; LVN480-500; LVN480-1000	LabTurbo Virus Mini Kit	Reagents for DNA and/or RNA extraction and preparation: bacteria and/or virus	Kit for viral nucleic acid extraction	15.90.40.01	All Others
5.	24C-LVX480-300; 24C-LVX480-500; 24C-LVX480-1000; LVX480-300; LVX480-500; LVX480-1000	LabTurbo Viral DNA/RNA Mini Kit	Reagents for DNA and/or RNA extraction and preparation: bacteria and/or virus	Kit for viral DNA + RNA extraction	15.90.40.01	All Others
6.	Acov11240; Acov13000	LabTurbo AIO COVID-19 RNA Testing Kit	Reagents for DNA and/or RNA amplification and/or detection: bacteria and/or virus	A real-time reverse transcription polymerase chain reaction (RT-PCR) diagnostic product for SARS-CoV-2 RNA (COVID-19) detection	15.90.40.02	All Others

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