



# CERTIFICATE OF IVD NOTIFICATION

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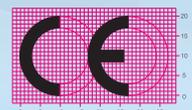
**Mr. G. Elkayam CEO**

**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/EDMS Code	Class
1.	HPBELI-03	Merilisa HBsAg	Enzyme immunoassay for the detection of HBsAg in human serum or plasma	As per pack insert	48319	List A
2.	HV3ELI-01	Merilisa HIV 1-2 Gen 3	Enzyme immunoassay for the detection of antibodies to Human Immunodeficiency Virus Type 1(HIV-1) and Type 2(HIV-2) in human serum or plasma	As per pack insert	48451	List A
3.	HV4ELI-05	Merilisa HIV Gen 4	Enzyme immunoassay for the detection of p24 antigen and antibodies to Human Immunodeficiency Virus Type 1(HIV-1) and Type 2(HIV-2) in human serum or plasma	As per pack insert	48445	List A
4.	SYPRPD-01 SYPRPD-02 RPDSYP-01	MERISCREEN Syphiline	One Step Test for Syphilis	As per pack insert	51801	Non Listed
5.	MFLRPD-05	MERISCREEN Malaria Pf/Pv Ag	One step test for Malaria Pf Pv Ag	As per pack insert	52311	Non Listed
6.	DNSELI-01 DNSELI-02	Merilisa / Dengue NS1 Ag	ELISA test for detection of Dengue NS1 Ag in human serum / plasma	As per pack insert	48912	Non Listed
7.	DTCRPD-02	MERISCREEN Dengue Onset	One step test for Dengue Ab (IgG/IgM) + NS1 Ag combo	As per pack insert	62928	Non Listed
8.	CKMELI-01	Covid Kavach Merilisa	Anti-SARS CoV -2 Human IgG ELISA	As per pack insert	64824	Non Listed
9.	NCTTAB-01 NCTTAB-02	MERISCREEN Covid-19 total antibody detection test	Covid-19 total antibody detection Rapid test	As per pack insert	64956	Non Listed
10.	NCTCAG-01 NCTCAG-02	MERISCREEN Covid-19 antigen detection test	Covid-19 antigen detection Rapid test	As per pack insert	64787	Non Listed



Obelis s.a.

Signature:

G. ELKAYAM  
C.E.O. SA

Date: 25/09/2020

Obelis s.a. - O.E.A.R.C.

Stamp:

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