



# E.A.R.-CERTIFICATE

(ART 10.3 of the Directive 98/79/EC on In Vitro Diagnostic)

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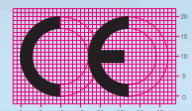
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## Annex A - List of Devices

(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.	NCVPCR-01 NCVPCR-02	MERIL	COVID-19 One-Step RT-PCR Kit	As per pack insert	64747	Non-Listed
2.	NCVRPD-01 NCVRPD-02 NCVRPD-03	MERIL	COVID-19 IgG/IgM Rapid Test	As per pack insert	64756	Non-Listed
3.	MHLRPD-02 MHLRPD-03 MHLRPD-04 MHLRPD-05	MERISCREEN Malaria Pf/Pan Ag	One Step Test for Malaria Pf/Pan Ag	As per pack insert	52311	Non-Listed
4.	MFLRPD-03 MFLRPD-04	MERISCREEN Malaria Pf/Pv Ag	One Step Test for Malaria Pf/Pv Ag	As per pack insert	52311	Non-Listed
5.	RPWMPH-02 RPWMPH-03 RPWMPH-04	MERISCREEN Malaria Pf HRP II Ag	One Step Test for Malaria Pf HRP II Ag	As per pack insert	52336	Non-Listed
6	HVWRPD-01 HVWRPD-02	MERISCREEN HIV 1-2 WB	One Step test Rapid Test for detection of anti-HIV in Human Serun/Plasma/Whole blood	As per pack insert	48447	List A
7	RPDHBV-01	MERISCREEN HBsAg	One Step Rapid Test for HBsAg	As per pack insert	48322	List A
8	RPDHCV-01	MERISCREEN HCV	One Step Rapid Test for HCV	As per pack insert	30829	List A
9	HPCELI-01	Merilisa HCV	Enzyme immunoassay for the detection of antibodies to Hepatitis C Virus in human serum or plasma	As per pack insert	48365	List A





