



CERTIFICATE OF IVD NOTIFICATION

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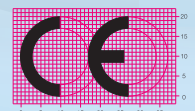
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Annex A - List of Devices

(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 / GIVD Code	Class
1.	PF09	DIAKEY COVID-19 IgM/IgG Rapid Test	DIAKEY COVID-19 IgM/IgG Rapid Test	Solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to COVID-19 in human whole blood, serum, plasma.	15.04.80.19	Others
2.	MF01	DIAKEY REALcheck COVID-19 (nCOV) Detection Kit	DIAKEY REALcheck COVID-19 (nCOV) Detection Kit	For the qualitative detection of nucleic acid from the COVID-19 in sputum, nasopharyngeal and oropharyngeal swabs specimens collected from individuals with signs and symptoms of infection who are suspected of COVID-19.	15.04.40.19	SA Others
3.	PF10	DIAKEY COVID-19 Ag Rapid Test	DIAKEY COVID-19 Ag Rapid Test	Immunochromatographic assay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal swab specimens from individuals who are suspected of COVID-19 by their healthcare provider.	15.04.80.19	Others

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