

## OF IVD NOTIFICATION

JROPEAN AUTHORIZED EPRESENTATIVE CENTER

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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
	PDC03	Virus Nucleic Acid Isolation Kit (Column based)	Extraction Kit	The Virus Nucleic Acid Isolation kit provides a fast simple and effective method for the isolation of viral DNA/ RNA from cell-free samples such as serum, plasma, body fluids and the supernatant of virus-infected cell cultures. Its unique buffer system will efficiently lyse cells and degrade protein, allowing for the nucleic acid to be easily bound by the glass fiber matrix of the column.	15.90.40.01	All others
2.	PDM04	Mbead Virus Genomic Nucleic Acid Kit (Mbeads Based)	Extraction Kit	MBead Virus Genomic Nucleic Acid Kit was designed specifically for genomic DNA/RNA isolation from Virus samples. Its special buffer system will efficiently lyse cell and degrade protein, allowing for DNA/RNA to be easily bound by the surface of the magnetic beads.	15.90.40.01	All Others

\*\* The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (MDD 93/42/EEC, article 2 & Annex IX; MEDDEV 2.4/1 Rev.9, chapter 3.1 & 3.3)

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