

DAC-SpectroMed S.R.L. Chisinau	Declaration of EC-Conformity	File No.	F-PS-10-05
		Rev. No.	1
	Product: Rapid tests for immunological and biochemical assays	Rev. Date	31-01-2017
		Doc.No	STD-DCE-376
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## DAC-SpectroMed SRL

Armeneasca str. 47, of. 64 MD-2012, Chisinau Republic of Moldova

hereby declares under its own responsibility that the *in-vitro diagnostics* medical devices:

**Immunochromatografic diagnostic rapid tests,**

assays listed in Annex I

- are classified as not listed in Annex I of the EC Council Directive 98/79/EC from 27<sup>th</sup> October, 1998 on in-vitro diagnostic medical devices;
- conform to the relevant provisions of the EC Council Directive 98/79/EC from 27<sup>th</sup> October 1998 on in-vitro diagnostic medical devices.

Harmonized standards applied:

EN ISO 9001:2008

EN ISO 14971:2012

EN ISO 18113-1:2011

EN ISO 18113-2:2011

EN ISO 23640:2011

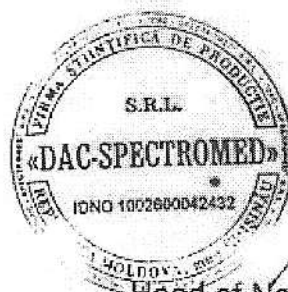
EN 13612:2002

EN ISO 15223-1:2012

EN ISO 13485:2012

DAC-SpectroMed SRL has a Quality System in place based on ISO 9001:2008 and ISO 13485:2012, certification is issued by the IQNet&SRAC.

Technical documentation demonstrating compliance is kept by the manufacturer and can be made available by the authorized representative in Europe: QARAD BV., Flight Forum 40, 5657 DB Eindhoven, The Netherlands.



  
General Manager  
Chireev Igor  
31.01.2017

Head of Normative-Technical Documentation  
and Certification Department

  
Emet Natalia  
31.01.2017



## Annex I

Declaration of Conformity according to European Directive of in vitro diagnostic medical devices (98/79/EG) of the Medical Devices Act (MPG)

Cat. No	Product	Method	Conformity
4190AS1	Anti-Syphilis-S-Strip-DAC	chromatographic immunoassay	CE
4191AS1	Anti-Syphilis-S-Cart-DAC	chromatographic immunoassay	CE
4195G1	Gonorrhea-Strip-DAC	chromatographic immunoassay	CE
4196G1	Gonorrhea-Cart-DAC	chromatographic immunoassay	CE
4293C1	Candida-Cart-DAC	chromatographic immunoassay	CE
4273C1	Candida/Trichomonas-Cart-DAC	chromatographic immunoassay	CE
4280T1	Trichomonas-Cart-DAC	chromatographic immunoassay	CE
4299H1	HPV 6/11-Cart-DAC	chromatographic immunoassay	CE
4300M1	Mycoplasma-Cart-DAC	chromatographic immunoassay	CE
4275U1	Ureaplasma-Cart-DAC	chromatographic immunoassay	CE
4271UM1	UU-MH Combo-Cart-DAC	chromatographic immunoassay	CE
4282IAB1	Influenza A/B 2-Panel-DAC	chromatographic immunoassay	CE
4186TB1	TB-S-Cart-DAC	chromatographic immunoassay	CE
4187MP1	MP Ab-S-Cart-DAC	chromatographic immunoassay	CE
4298V1	Vaginosis-Cart-DAC	chromatographic immunoassay	CE
4215HP1	HP-Cart-DAC	chromatographic immunoassay	CE
4250HP1	HP-F-Cart-DAC	chromatographic immunoassay	CE
4217M1	Malaria P.f/P.v Ab-Cart-DAC	chromatographic immunoassay	CE
4218M1	Malaria P.f Ag-Cart-DAC	chromatographic immunoassay	CE
4220D1	Dengie IgG/IgM-Cart-DAC	chromatographic immunoassay	CE
4274BU1	BU-Cart-DAC	chromatographic immunoassay	CE
4214SA1	Streptococ A-Cart-DAC	chromatographic immunoassay	CE
4276SB1	Streptococ B-Cart-DAC	chromatographic immunoassay	CE
4277A1	Adeno-Cart-DAC	chromatographic immunoassay	CE
4278R1	Rota-Cart-DAC	chromatographic immunoassay	CE
4279AR1	Adeno/Rota-Cart-DAC	chromatographic immunoassay	CE
4281M1	Mononucleosis-S-WB-Cart-DAC	chromatographic immunoassay	CE
4290EC01	E.Coli-Cart-DAC	chromatographic immunoassay	CE
4291L1	Listeria-Cart-DAC	chromatographic immunoassay	CE
4292S1	Salmonella-Cart-DAC	chromatographic immunoassay	CE
4224HSVII1	HSV-II-Cart-DAC-IgG/IgM	chromatographic immunoassay	CE
4150HCG-2,5	HCG-U-Strip-DAC-2,5	chromatographic immunoassay	CE
4151HCG-3,5	HCG-U-Strip-DAC-3,5	chromatographic immunoassay	CE
4152HCG 31	HCG-U-Cart-DAC	chromatographic immunoassay	CE
4155HCG1	HCG-SU-Strip-DAC	chromatographic immunoassay	CE
4153HCG1	HCG-SU-Cart-DAC	chromatographic immunoassay	CE
4154HCG1	HCG-M-Cart-DAC	chromatographic immunoassay	CE
4160LH1	LH-U-Strip-DAC	chromatographic immunoassay	CE
4161LH1	LH-U-Cart-DAC	chromatographic immunoassay	CE
4162LH1	LH-M-Cart-DAC	chromatographic immunoassay	CE
4156FSH1	FSH-U-Strip-DAC	chromatographic immunoassay	CE
4157FSH1	FSH-U-Cart-DAC	chromatographic immunoassay	CE
4158FSH1	FSH-M-Cart-DAC	chromatographic immunoassay	CE
4211M1	Myo-S-Cart-DAC	chromatographic immunoassay	CE
4209T1	Tn I-S-Cart-DAC	chromatographic immunoassay	CE
4209TWB1	Tn I-WB-Cart-DAC	chromatographic immunoassay	CE
4221MB1	CK-MB-S-Cart-DAC	chromatographic immunoassay	CE
4219AMI1	AMI-S-Panel-DAC	chromatographic immunoassay	CE
4296N1	NT-proBNP-Cart-DAC	chromatographic immunoassay	CE
4297H1	H-FABP-Cart-DAC	chromatographic immunoassay	CE
4204CEA1	CEA-S-Strip-DAC	chromatographic immunoassay	CE
4205CEA1	CEA-S-Cart-DAC	chromatographic immunoassay	CE
4198AFP1	AFP-S-Strip-DAC	chromatographic immunoassay	CE
4199AFP1	AFP-S-Cart-DAC	chromatographic immunoassay	CE
4201FOB1	FOB-F-Strip-DAC	chromatographic immunoassay	CE
4202FOB1	FOB-F-Cart-DAC	chromatographic immunoassay	CE
4200C1	CTCC-Cart-DAC	chromatographic immunoassay	CE
4232AMP1	AMP-Strip-DAC	chromatographic immunoassay	CE
4233AMP1	AMP-Cart-DAC	chromatographic immunoassay	CE
4244BAR1	BAR-Strip-DAC	chromatographic immunoassay	CE
4245BAR1	BAR-Cart-DAC	chromatographic immunoassay	CE
4247BZ01	BZO-Strip-DAC	chromatographic immunoassay	CE
4248BZ01	BZO-Cart-DAC	chromatographic immunoassay	CE
4226COC1	COC-Strip-DAC	chromatographic immunoassay	CE
4227COC1	COC-Cart-DAC	chromatographic immunoassay	CE
4258MDMA1	MDMA-Strip-DAC	chromatographic immunoassay	CE
4259MDMA1	MDMA-Cart-DAC	chromatographic immunoassay	CE
4235mAMP1	mAMP-Strip-DAC	chromatographic immunoassay	CE
4236mAMP1	mAMP-Cart-DAC	chromatographic immunoassay	CE
4229MOP1	MOP-Strip-DAC	chromatographic immunoassay	CE



Cat. No	Product	Method	Cornformity
4230MOP1	MOP-Cart-DAC	chromatographic immunoassay	CE
4238MTD1	MTD-Strip-DAC	chromatographic immunoassay	CE
4239MTD1	MTD-Cart-DAC	chromatographic immunoassay	CE
4261OPI1	OPI-Strip-DAC	chromatographic immunoassay	CE
4262OPI1	OPI-Cart-DAC	chromatographic immunoassay	CE
4241THC1	THC-Strip-DAC	chromatographic immunoassay	CE
4242THC1	THC-Cart-DAC	chromatographic immunoassay	CE
4264TCA1	TCA-Strip-DAC	chromatographic immunoassay	CE
4265TCA1	TCA-Cart-DAC	chromatographic immunoassay	CE
4267PCP1	PCP-Strip-DAC	chromatographic immunoassay	CE
4268PCP1	PCP-Cart-DAC	chromatographic immunoassay	CE
4253D2	2-Drugs-DAC	chromatographic immunoassay	CE
4254D3	3-Drugs-DAC	chromatographic immunoassay	CE
4255D4	4-Drugs-DAC	chromatographic immunoassay	CE
4256D5	5-Drugs-DAC	chromatographic immunoassay	CE
4251D6	6-Drugs-DAC	chromatographic immunoassay	CE
4257D10	10-Drugs-DAC	chromatographic immunoassay	CE
4252D12	12-Drugs-DAC	chromatographic immunoassay	CE
4216A1	Alcohol-Strip-DAC	chromatographic immunoassay	CE
4203A1	Alcohol-U-Strip-DAC	chromatographic immunoassay	CE
4270CRP1	CRP-Cart-DAC	chromatographic immunoassay	CE
4272IgE1	IgE-S-Cart-DAC	chromatographic immunoassay	CE
4283AU1	Albumin Urine-Cart-DAC	chromatographic immunoassay	CE
4284hsCRP1	hsCRP-Cart-DAC	chromatographic immunoassay	CE
4285DD1	D-Dimer-Cart-DAC	chromatographic immunoassay	CE
4286RF1	RF- S-WB-Cart-DAC	chromatographic immunoassay	CE
4287NTSH1	Neonatal TSH-WB-Cart-DAC	chromatographic immunoassay	CE
4288TSH1	TSH-S-WB-Cart-DAC	chromatographic immunoassay	CE
4289F1	Ferritin-WB-S-Cart-DAC	chromatographic immunoassay	CE
4294P1	Procalcitonin-Cart-DAC	chromatographic immunoassay	CE
4295IG1	IGFBP-1-Cart-DAC	chromatographic immunoassay	CE





Cat. No	Product	Method	Cornformity
1033C100	CRP-Latex	Slide agglunation	CE
1033C200	CRP-Latex	Slide agglunation	CE
1033C250	CRP-Latex	Slide agglunation	CE
1033C500	CRP-Latex	Slide agglunation	CE
1031A100	ASLO-DAC	Slide agglunation	CE
1031A200	ASLO-DAC	Slide agglunation	CE
1031A250	ASLO-DAC	Slide agglunation	CE
1031A500	ASLO-DAC	Slide agglunation	CE
1039R100	RefaTex-DAC	Slide agglunation	CE
1039R200	RefaTex-DAC	Slide agglunation	CE
1039R250	RefaTex-DAC	Slide agglunation	CE
1039R500	RefaTex-DAC	Slide agglunation	CE
1038R200	RefaTex-conf	Slide agglunation	CE
1041R100	ReumoScreen-DAC	Slide agglunation	CE
1045W100	Waalser-Rose-DAC	Slide agglunation	CE
1035I100	IM-DAC	Slide agglunation	CE
1040R100	RPR-Carbon-DAC	Slide agglunation	CE
1040R250	RPR-Carbon-DAC	Slide agglunation	CE
1040R500	RPR-Carbon-DAC	Slide agglunation	CE
1040R1000	RPR-Carbon-DAC	Slide agglunation	CE
1043S100	SLE-DAC	Slide agglunation	CE
1044T100	TPHA-DAC	Microplate agglutination	CE
1044T200	TPHA-DAC	Microplate agglutination	CE
1047C100	Candida-Latex	Slide agglunation	CE
1049T100	Trihomono-Latex	Slide agglunation	CE
1051D50	D-dimer-DAC	Slide agglunation	CE
1054A50	AntiSperm-Latex	Slide agglunation	CE
1053A50	AntiOvary-Latex	Slide agglunation	CE
1032C435	CIC-DAC	End point	CE
1036N305	NBT-DAC	End point	CE
4051G100	DAC-1G	Paper-thin layer chromatography	CE
4055K100	DAC-1K	Paper-thin layer chromatography	CE
4057B100	DAC-1B	Paper-thin layer chromatography	CE
4059P100	DAC-1P	Paper-thin layer chromatography	CE
4070CM50	DAC-2CM	Paper-thin layer chromatography	CE
4070CM100	DAC-2CM	Paper-thin layer chromatography	CE
4066GK100	DAC-2GK	Paper-thin layer chromatography	CE
4068GP100	DAC-2GP	Paper-thin layer chromatography	CE
4076P100	DAC-3	Paper-thin layer chromatography	CE
4083B100	DAC-4B	Paper-thin layer chromatography	CE
4087S100	DAC-4S	Paper-thin layer chromatography	CE
4091D100	DAC-5	Paper-thin layer chromatography	CE
4101D100	DAC-7	Paper-thin layer chromatography	CE
4103N100	DAC-8	Paper-thin layer chromatography	CE
4113D100	DAC-9	Paper-thin layer chromatography	CE
4117D100	DAC-10	Paper-thin layer chromatography	CE
4121D100	DAC-11	Paper-thin layer chromatography	CE
4124D50	DAC-12	Paper-thin layer chromatography	CE
4124D100	DAC-12	Paper-thin layer chromatography	CE
4062UC24	UreControl-DAC	Paper-thin layer chromatography	CE

