

DAC-SpectroMed S.R.L. Chisinau	Declaration of EC-Conformity	File No.	F-PS-10-05
		Rev. No.	1
	Product: ELISA	Rev. Date	28-11-2014
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DAC-SpectroMed SRL

Armeneasca str. 47, ap. 64 MD-2012, Chisinau Republica Moldova

hereby declares under its own responsibility that the *in-vitro diagnostics* medical devices **listed in Annex I**

- are classified as a “all other IVD Medical Devices” according to Annex I of the EC Council Directive 98/79/EC from 27th October 1998 on in-vitro diagnostic medical devices;
- are classified as not listed in Annex II of the EC Council Directive 98/79/EC from 27th October 1998 on in-vitro diagnostic medical devices;
- conform to the relevant provisions of the EC Council Directive 98/79/EC from 27th 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 23640:2011

EN 13612:2002

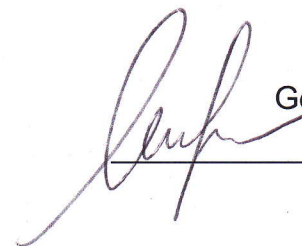
EN ISO 15223-1:2012

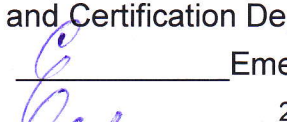
EN ISO 13485:2012

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
28.11.2014

Head of Normative-Technical Documentation
and Certification Department

Emet Natalia
28.11.2014

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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
4501T96	T3-DAC	Microplate Enzyme Immunoassay	CE
4501T192	T3-DAC	Microplate Enzyme Immunoassay	CE
4502T96	ft3-DAC	Microplate Enzyme Immunoassay	CE
4502T192	ft3-DAC	Microplate Enzyme Immunoassay	CE
4503T96	T4-DAC	Microplate Enzyme Immunoassay	CE
4503T192	T4-DAC	Microplate Enzyme Immunoassay	CE
4504T96	ft4-DAC	Microplate Enzyme Immunoassay	CE
4504T192	ft4-DAC	Microplate Enzyme Immunoassay	CE
4505AT96	Anti-TPO-DAC	Microplate Enzyme Immunoassay	CE
4506T96	TSH-DAC	Microplate Enzyme Immunoassay	CE
4506T192	TSH-DAC	Microplate Enzyme Immunoassay	CE
4507P96	Prolactin-DAC	Microplate Enzyme Immunoassay	CE
4508T96	Testosterone-DAC	Microplate Enzyme Immunoassay	CE
4508T192	Testosterone-DAC	Microplate Enzyme Immunoassay	CE
4509T96	fTestosterone-DAC	Microplate Enzyme Immunoassay	CE
4509T192	fTestosterone-DAC	Microplate Enzyme Immunoassay	CE
4511P96	PSA-DAC	Microplate Enzyme Immunoassay	CE
4511P192	PSA-DAC	Microplate Enzyme Immunoassay	CE
4515P96	fPSA-DAC	Microplate Enzyme Immunoassay	CE
4515P192	fPSA-DAC	Microplate Enzyme Immunoassay	CE
4515P192	fPSA-DAC	Microplate Enzyme Immunoassay	CE
4517HP96	Anti-H.Pylori IgG-DAC	Microplate Enzyme Immunoassay	CE
4518HP96	Anti-H.Pylori IgM-DAC	Microplate Enzyme Immunoassay	CE
4519HP96	Anti-H.Pylori IgA-DAC	Microplate Enzyme Immunoassay	CE
4514CP96	C-Peptide-DAC	Microplate Enzyme Immunoassay	CE
4514CP192	C-Peptide-DAC	Microplate Enzyme Immunoassay	CE
4521AF96	AFP-DAC	Microplate Enzyme Immunoassay	CE
4521AF192	AFP-DAC	Microplate Enzyme Immunoassay	CE
4523C96	CA 19-9-DAC	Microplate Enzyme Immunoassay	CE
4523C192	CA 19-9-DAC	Microplate Enzyme Immunoassay	CE
4525C96	CA 125-DAC	Microplate Enzyme Immunoassay	CE
4525C192	CA 125-DAC	Microplate Enzyme Immunoassay	CE
4526C96	CEA-DAC	Microplate Enzyme Immunoassay	CE
4526C192	CEA-DAC	Microplate Enzyme Immunoassay	CE
4528F96	Ferritin-DAC	Microplate Enzyme Immunoassay	CE

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Cat. No	Product	Method	Conformity
4530AT96	Anti-TG-DAC	Microplate Enzyme Immunoassay	CE
4540F96	FSH-DAC	Microplate Enzyme Immunoassay	CE
4540F192	FSH-DAC	Microplate Enzyme Immunoassay	CE
4542D96	DHEA-S-DAC	Microplate Enzyme Immunoassay	CE
4542D192	DHEA-S-DAC	Microplate Enzyme Immunoassay	CE
4544L96	LH-DAC	Microplate Enzyme Immunoassay	CE
4544L192	LH-DAC	Microplate Enzyme Immunoassay	CE
4546P96	Progesteron-DAC	Microplate Enzyme Immunoassay	CE
4546P192	Progesteron-DAC	Microplate Enzyme Immunoassay	CE
4534M18	Multi Control-DAC	Microplate Enzyme Immunoassay	CE
4551IA96	IgA-DAC	Microplate Enzyme Immunoassay	CE
4553IG96	IgG-DAC	Microplate Enzyme Immunoassay	CE
4555IM96	IgM-DAC	Microplate Enzyme Immunoassay	CE
4557CA96	CA-153-DAC	Microplate Enzyme Immunoassay	CE
4559H96	HCG-DAC	Microplate Enzyme Immunoassay	CE
4560H96	βHCG-DAC	Microplate Enzyme Immunoassay	CE
4562C96	CRP-DAC	Microplate Enzyme Immunoassay	CE
4564T96	TG-DAC	Microplate Enzyme Immunoassay	CE
4570C18	TG Control-DAC	Microplate Enzyme Immunoassay	CE
4566E96	Estadiol-DAC	Microplate Enzyme Immunoassay	CE
4568C96	Cortisol-DAC	Microplate Enzyme Immunoassay	CE
4572H6	H.Pylori Control-DAC	Microplate Enzyme Immunoassay	CE
4574AT6	Anti-TG & Anti-TPO Control-DAC	Microplate Enzyme Immunoassay	CE
4576C96	CA-72-4-DAC	Microplate Enzyme Immunoassay	CE
4578C96	Calcitonin-DAC	Microplate Enzyme Immunoassay	CE
4580P96	Parathormon-DAC	Microplate Enzyme Immunoassay	CE
4581C96	Complexe imune circulante (CIC)-DAC	Microplate Enzyme Immunoassay	CE