

DAC-SpectroMed S.R.L. Chisinau	Declaration of EC-Conformity	File No.	F-PS-10-05
		Rev. No.	2
		Rev. Date	07-16-2019
		Page	1 / 2

DAC-SpectroMed SRL
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hereby declares under its own responsibility that the *in-vitro diagnostics* medical devices for haemostasis evaluation **listed in Annex I**

- are in accordance with the Annex I 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 9001:2015
 EN ISO 14971:2012
 EN ISO 18113-1:2011
 EN ISO 18113-2:2011
 EN ISO 23640:2011
 EN ISO 13612:2002
 EN ISO 15223-1:2012
 EN ISO 13485:2016

DAC-SpectroMed SRL has a Quality System in place based on EN ISO 9001:2015 and EN ISO 13485:2016, issued by the IQNet&SRAC.

Our Authorized Representative in EU is Qarad B.V., with address at Flight Forum 40, 5657 DB Eindhoven, The Netherlands




 General Manager
 Virschi Roman
 16.07.2019

Head of Normative-Technical Documentation
 and Certification Department

 Emet Natalia
 16.07.2019

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
4005A160	APTT-DAC-EA	Coagulation time	CE
4008H350	Haemostaz-DAC-I	Coagulation time	CE
4010H100	Haemostaz-DAC-II	Coagulation time	CE
4013P100	Prothrombin-DAC.Lq ISI	Coagulation time	CE
4013P200	Prothrombin-DAC.Lq ISI	Coagulation time	CE
4012P100	Prothrombin-DAC-ISI	Coagulation time	CE
4012P240	Prothrombin-DAC-ISI	Coagulation time	CE
4012P300	Prothrombin-DAC-ISI	Coagulation time	CE
4011P80	Prothrombin-DAC-mono ISI	Coagulation time	CE
4011P200	Prothrombin-DAC-mono ISI	Coagulation time	CE
4011P4x10	Prothrombin-DAC-mono ISI	Coagulation time	CE
4011P500	Prothrombin-DAC-mono ISI	Coagulation time	CE
4015T120	Thrombin-DAC-mono	Coagulation time	CE
4015T300	Thrombin-DAC-mono	Coagulation time	CE
4020F160	Fibrinogen-DAC	Coagulation time	CE
4020F400	Fibrinogen-DAC	Coagulation time	CE
4022I60	Imidasol-DAC	Coagulation time	CE
4024C64	Calcium Chloride-DAC	Coagulation time	CE
4006C2	Coagulo-cont N	Coagulation time	CE
4007C2	Coagulo-cont P	Coagulation time	CE
4030C2	Coagulo-cont P+	Coagulation time	CE
4032C2	Control Plasma L1	Coagulation time	CE
4033C2	Control Plasma L2	Coagulation time	CE
4018C1	Coagulo-St-DAC	Coagulation time	CE