

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

**DAC-SpectroMed SRL**  
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**MD-2025, Chisinau**  
**Republic of Moldova**

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

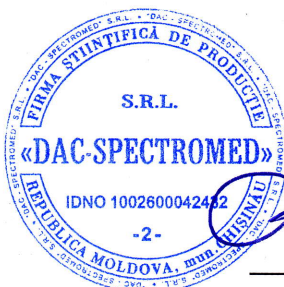
- are in accordance with the Annex I of the EC Council Directive 98/79/EC from 27<sup>th</sup> October 1998 on in-vitro diagnostic medical devices;
- conform to the relevant provisions of the EC Council Directive 98/79/EC from 27<sup>th</sup> October 1998 on in-vitro diagnostic medical devices.

Harmonized standards applied:

EN ISO 9001:2015  
 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  
 11.10.2021

Tehnolog Principal  
 Emet Natalia  
 11.10.2021

## Annex I

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

<b>Cat. No</b>	<b>Product</b>	<b>Method</b>	<b>Cornformity</b>
4005A25	APTT-DAC-EA	Coagulation time	CE
4005A50	APTT-DAC-EA	Coagulation time	CE
4005A100	APTT-DAC-EA	Coagulation time	CE
4005A160	APTT-DAC-EA	Coagulation time	CE
4005A200	APTT-DAC-EA	Coagulation time	CE
4008H350	Haemostaz-DAC-I	Coagulation time	CE
4010H100	Haemostaz-DAC-II	Coagulation time	CE
4013P25	Prothrombin-DAC.Lq ISI	Coagulation time	CE
4013P50	Prothrombin-DAC.Lq ISI	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
4020F60	Fibrinogen-DAC	Coagulation time	CE
4020F120	Fibrinogen-DAC	Coagulation time	CE
4020F400	Fibrinogen-DAC	Coagulation time	CE
4022I60	Imidasol-DAC	Coagulation time	CE
4024C64	Calcium Choride-DAC	Coagulation time	CE
4006C2	Coagulo-cont N	Coagulation time	CE
4006C3	Coagulo-cont N	Coagulometric	CE
4006C10	Coagulo-cont N	Coagulometric	CE
4007C2	Coagulo-cont P	Coagulation time	CE
4007C3	Coagulo-cont P	Coagulometric	CE
4007C10	Coagulo-cont P	Coagulometric	CE
4030C2	Coagulo-cont P+	Coagulation time	CE
4032C2	Control Plasma L1	Coagulation time	CE
4033C2	Control Plasma L2	Coagulation time	CE
4034C2	Control Plasma L2+	Coagulation time	CE
4018C1	Coagulo-St-DAC	Coagulation time	CE