DSM 4.2.0.1 Version Nr. 2	**Declaration of EC-Conformity**

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 **listed in Annex I-II**

- are classified as a "all other IVD Medical Devices" according to Annex II of the EC Council Directive 98/79/EC from 27th October 1998 on in-vitro diagnostic medical devices;
- are in accordance with the Annex III 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:
DIN EN ISO 9001:2008
DIN EN ISO 14971:2009
DIN EN ISO 18113-1:2009
DIN EN ISO 62366:2008
DIN EN ISO 13640:2002
DIN EN ISO 13612:2002
DIN EN ISO 18113-2:2009
DIN EN ISO 13975:2003
DIN EN ISO 980:2008
DIN EN ISO 13485:2003

DAC-SpectroMed SRL has a Quality System in place based on EN ISO 9001:2008 and EN ISO 13485:2003, issued by the IQNet&SRAC.

General Manager
Chireev Igor
16.05.2013

Head of Normative-Technical Documentation and Certification Department
Emet Natalia
16.05.2013

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REPUBLICA MOLDOVA mun. CHISINAU PENTRU FACTURI S.R.L. "PROFILAXIA DIAGNOSTIC" SOCIETATEA CU RASPUNDERE LIMITATA