

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

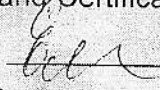
DAC-SpectroMed SRL has a Quality System in place based on EN ISO 9001:2008 and EN ISO 13485:2003, issued by the IQNet&SRAC.

General Manager

Chireev Igor

16.05.2013

Head of Normative-Technical Documentation
and Certification Department

Emet Natalia

16.05.2013

