DAC-SpectroMed S.R.L. Chisinau	Declaration of EC-Conformity	File No.	F-PS-10-05
		Rev. No.	0
	Product: IgE-DAC	Rev. Date	25-04-2016
		Doc.No	STD-DCE-325
		Page	1 / 1

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:

IgE-DAC

REF 4538I96 96 tests

REF 4538I192 192 tests

- 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 18113-2:2011

EN ISO 23640:2011

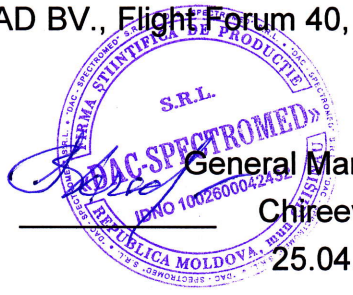
EN 13612:2002

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

25.04.2016

Head of Normative-Technical Documentation and Certification Department

Emet Natalia

25.04.2016