

DAC-SpectroMed S.R.L. Chisinau	Declaration of EC-Conformity	File No.	F-PS-10-05
		Rev. No.	2
	Product: Drugs-DAC	Rev. Date	07-16-2019
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DAC-SpectroMed SRL

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hereby declares under its own responsibility that the *in-vitro diagnostics* medical devices:

2-Drugs-DAC	REF	4253D2	1 test
3-Drugs-DAC	REF	4254D3	1 test
4-Drugs-DAC	REF	4255D4	1 test
5-Drugs-DAC	REF	4256D5	1 test
6-Drugs-DAC	REF	4251D6	1 test
10-Drugs-DAC	REF	4257D10	1 test

- 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 9001:2015	EN ISO 23640:2011
EN ISO 14971:2012	EN ISO 13612:2002
EN ISO 18113-1:2011	EN ISO 15223-1:2012
EN ISO 18113-2:2011	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
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16.07.2019

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