

DAC-SpectroMed S.R.L. Chisinau	Declaration of EC-Conformity	File No.	F-PS-10-05
		Rev. No.	4
	Product: RPR-Carbon-DAC	Rev. Date	09-05-2022
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DAC-SpectroMed SRL

Nicolae Testemitanu str. 37, MD-2025, Chisinau, Republic of Moldova

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

RPR-Carbon-DAC

REF	1040R100	100 tests
REF	1040R250	250 tests
REF	1040R500	500 tests
REF	1040R1000	1000 tests
REF	1040R250D	250 tests
REF	1040R500D	500 tests

- are classified as neither listed in Annex II nor for self-testing according to 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.

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 EC-REP BV, with address at Pas 257, 2440 Geel, Belgium.

General Manager

_____ Mordvinov Ghenadie
05.09.2022

Specialist of Normative-Technical Documentation
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_____Anghelova Ana
05.09.2022