

<b>DAC-SpectroMed S.R.L.</b> <b>Chisinau</b>	<b>Declaration of EC-Conformity</b>	File No.	F-PS-10-05
		Rev. No.	4
	<b>Product: RPR-Carbon-DAC</b>	Rev. Date	03-05-2024
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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:

Product/Trade Name	Catalogue Number	Intended Purpose
RPR-Carbon-DAC	1040R100	set of reagents for serological analyses
RPR-Carbon-DAC	1040R100P	set of reagents for serological analyses
RPR-Carbon-DAC	1040R250	set of reagents for serological analyses
RPR-Carbon-DAC	1040R250D	set of reagents for serological analyses
RPR-Carbon-DAC	1040R500	set of reagents for serological analyses
RPR-Carbon-DAC	1040R500D	set of reagents for serological analyses
RPR-Carbon-DAC	1040R1000	set of reagents for serological analyses

Risk Class: Class B according to Rule 4 of Annex VIII of the IVDR 2017/746.

to which this declaration relates comply with the provision of the following relevant Union legislation:

- Regulation (EU) 2017/746 of the European Parliament and of the of 5 April 2017 on in vitro diagnostic medical devices.

The following conformity assessment procedure has been followed

- Annex IX Conformity Assessment based on a Quality Management System and on assessment of technical documentation.

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  
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05.03.2024



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05.03.2024