DAC-SpectroMed S.R.L. Chisinau	Declaration of EC-Conformity	File No.	F-PS-10-05
		Rev. No.	1
	Product: Clean Cell-DAC	Rev. Date	02-27-2024
		Doc.No	STD-DCE-395
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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
Clean Cell-DAC <5 %	3239C100	washing solution
Clean Cell-DAC <5 %	3239C500	washing solution
Clean Cell-DAC <5 %	3239C1000	washing solution
Clean Cell-DAC <1 %	3241C100	washing solution
Clean Cell-DAC <1 %	3241C500	washing solution
Clean Cell-DAC <1 %	3241C1000	washing solution
Clean Cell-DAC <0,5 %	3243C100	washing solution
Clean Cell-DAC <0,5 %	3243C500	washing solution
Clean Cell-DAC <0,5 %	3243C1000	washing solution

Risk Class: Class A according to Rule 5 of Annex VIII of the IVDR 2017/746.

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

- 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(s) has(ve) been followed

- Annex IX Conformity Assessment based on a Quality Management System and on assessment of technical documentation.
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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
27.02.2024

Specialist of Normative-Technical Documentation and Certification Department
Anghelova Ana
27.02.2024

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