DAC-SpectroMed S.R.L. Chisinau	Declaration of EC-Conformity	File No.	F-PS-10-05
		Rev. No.	3
	Product: Fibrinogen-DAC	Rev. Date	10-20-2021
		Doc.No	STD-DCE-102
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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:

Fibrinogen-DAC

REF	4020F60	1x3 ml
REF	4020F120	2x3 ml
REF	4020F160	4x2 ml
REF	4020F400	6x3 ml

- 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 14971:2012
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 23640:2011
EN ISO 13612:2002
EN ISO 15223-1:2012
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.

FIRMA STIINTIFICA DE PRODUCTIE S.R.L. «DAC-SPECTROMED» IDNO 1002600042432 -2- REPUBLICA MOLDOVA, mun. CHISINAU

General Manager
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20.10.2021

Head of Normative-Technical Documentation and Certification Department
Emet Natalia
20.10.2021

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