DAC-SpectroMed S.R.L. Chisinau	Declaration of EC-Conformity	File No.	F-PS-10-05
		Rev. No.	2
	Product: DAC-11	Rev. Date	07-16-2019
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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:

DAC-11

REF 4121D100 100 tests

REF 4121D150 150 tests

- 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 ȘTIINȚIFICĂ DE PRODUCȚIE S.R.L. «DAC-SPECTROMED» IDNO 1002600042432 -2- REPUBLICA MOLDOVA, mun. CHISINAU

General Manager
Virschi Roman
16.07.2019

Head of Normative-Technical Documentation
and Certification Department
Emet Natalia
16.07.2019

Digitally signed by Stoianova Elena
Date: 2026.02.18 12:59:33 EET
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