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
RefaTex-DAC	1039R100	set of reagents for serological analyses
RefaTex-DAC	1039R200	set of reagents for serological analyses
RefaTex-DAC	1039R250	set of reagents for serological analyses
RefaTex-DAC	1039R500	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
Mordvinov Ghenadie
05.03.2024

Specialist of Normative-Technical Documentation
and Certification Department
Anghelova Ana
05.03.2024

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