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|-----------------------------------|------------------------------|-----------|-------------|
| DAC-SpectroMed S.R.L.<br>Chisinau | Declaration of EC-Conformity | File No.  | F-PS-10-05  |
|                                   |                              | Rev. No.  | 2           |
|                                   | Product: Prothrombin-DAC-ISI | Rev. Date | 07-16-2019  |
|                                   |                              | Doc.No    | STD-DCE-108 |
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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:

### Prothrombin-DAC-ISI

|              |        |
|--------------|--------|
| REF 4012P100 | 2x5 ml |
| REF 4012P240 | 6x4 ml |
| REF 4012P300 | 6x5 ml |

are classified as not listed in Annex II of the EC Council Directive 98/79/EC from 27<sup>th</sup> October 1998 on in-vitro diagnostic medical devices;

- conform to the relevant provisions of the EC Council Directive 98/79/EC from 27<sup>th</sup> 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

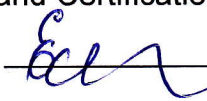
DAC-SpectroMed SRL has a Quality System in place based on EN ISO 9001:2015 and EN ISO 13485:2016, issued by the IQNet&SRAC.

Our Authorized Representative in EU is Qarad B.V., with address at Flight Forum 40, 5657 DB Eindhoven, The Netherlands.



  
 General Manager  
 Virschi Roman  
 16.07.2019

Head of Normative-Technical Documentation  
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 16.07.2019