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|-----------------------------------|---|-----------|-------------|
| DAC-SpectroMed S.R.L.<br>Chisinau | Declaration of EC-Conformity  | File No.  | F-PS-10-05  |
|                                   |   | Rev. No.  | 1           |
|                                   | Product:<br>Rapid tests for immunological and<br>biochemical assays | Rev. Date | 31-01-2017  |
|                                   |   | Doc.No    | STD-DCE-376 |
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## DAC-SpectroMed SRL

Armeneasca str. 47, of. 64 MD-2012, Chisinau Republic of Moldova

hereby declares under its own responsibility that the *in-vitro diagnostics* medical devices:

**Immunochromatografic diagnostic rapid tests,**

assays listed in Annex I

- are classified as not listed in Annex I 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 9001:2008

EN ISO 14971:2012

EN ISO 18113-1:2011

EN ISO 18113-2:2011

EN ISO 23640:2011

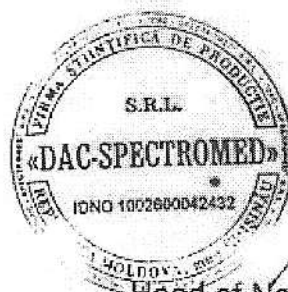
EN 13612:2002

EN ISO 15223-1:2012

EN ISO 13485:2012

DAC-SpectroMed SRL has a Quality System in place based on ISO 9001:2008 and ISO 13485:2012, certification is issued by the IQNet&SRAC.

Technical documentation demonstrating compliance is kept by the manufacturer and can be made available by the authorized representative in Europe: QARAD BV., Flight Forum 40, 5657 DB Eindhoven, The Netherlands.



  
General Manager  
Chireev Igor  
31.01.2017

Head of Normative-Technical Documentation  
and Certification Department

  
Emet Natalia  
31.01.2017



## Annex I

Declaration of Conformity according to European Directive of in vitro diagnostic medical devices (98/79/EG) of the Medical Devices Act (MPG)

| Cat. No     | Product                      | Method                      | Conformity |
|-------------|------------------------------|-----------------------------|------------|
| 4190AS1     | Anti-Syphilis-S-Strip-DAC    | chromatographic immunoassay | CE         |
| 4191AS1     | Anti-Syphilis-S-Cart-DAC     | chromatographic immunoassay | CE         |
| 4195G1      | Gonorrhea-Strip-DAC          | chromatographic immunoassay | CE         |
| 4196G1      | Gonorrhea-Cart-DAC           | chromatographic immunoassay | CE         |
| 4293C1      | Candida-Cart-DAC             | chromatographic immunoassay | CE         |
| 4273C1      | Candida/Trichomonas-Cart-DAC | chromatographic immunoassay | CE         |
| 4280T1      | Trichomonas-Cart-DAC         | chromatographic immunoassay | CE         |
| 4299H1      | HPV 6/11-Cart-DAC            | chromatographic immunoassay | CE         |
| 4300M1      | Mycoplasma-Cart-DAC          | chromatographic immunoassay | CE         |
| 4275U1      | Ureaplasma-Cart-DAC          | chromatographic immunoassay | CE         |
| 4271UM1     | UU-MH Combo-Cart-DAC         | chromatographic immunoassay | CE         |
| 4282IAB1    | Influenza A/B 2-Panel-DAC    | chromatographic immunoassay | CE         |
| 4186TB1     | TB-S-Cart-DAC                | chromatographic immunoassay | CE         |
| 4187MP1     | MP Ab-S-Cart-DAC             | chromatographic immunoassay | CE         |
| 4298V1      | Vaginosis-Cart-DAC           | chromatographic immunoassay | CE         |
| 4215HP1     | HP-Cart-DAC                  | chromatographic immunoassay | CE         |
| 4250HP1     | HP-F-Cart-DAC                | chromatographic immunoassay | CE         |
| 4217M1      | Malaria P.f/P.v Ab-Cart-DAC  | chromatographic immunoassay | CE         |
| 4218M1      | Malaria P.f Ag-Cart-DAC      | chromatographic immunoassay | CE         |
| 4220D1      | Dengie IgG/IgM-Cart-DAC      | chromatographic immunoassay | CE         |
| 4274BU1     | BU-Cart-DAC                  | chromatographic immunoassay | CE         |
| 4214SA1     | Streptococ A-Cart-DAC        | chromatographic immunoassay | CE         |
| 4276SB1     | Streptococ B-Cart-DAC        | chromatographic immunoassay | CE         |
| 4277A1      | Adeno-Cart-DAC               | chromatographic immunoassay | CE         |
| 4278R1      | Rota-Cart-DAC                | chromatographic immunoassay | CE         |
| 4279AR1     | Adeno/Rota-Cart-DAC          | chromatographic immunoassay | CE         |
| 4281M1      | Mononucleosis-S-WB-Cart-DAC  | chromatographic immunoassay | CE         |
| 4290EC01    | E.Coli-Cart-DAC              | chromatographic immunoassay | CE         |
| 4291L1      | Listeria-Cart-DAC            | chromatographic immunoassay | CE         |
| 4292S1      | Salmonella-Cart-DAC          | chromatographic immunoassay | CE         |
| 4224HSVII1  | HSV-II-Cart-DAC-IgG/IgM      | chromatographic immunoassay | CE         |
| 4150HCG-2,5 | HCG-U-Strip-DAC-2,5          | chromatographic immunoassay | CE         |
| 4151HCG-3,5 | HCG-U-Strip-DAC-3,5          | chromatographic immunoassay | CE         |
| 4152HCG 31  | HCG-U-Cart-DAC               | chromatographic immunoassay | CE         |
| 4155HCG1    | HCG-SU-Strip-DAC             | chromatographic immunoassay | CE         |
| 4153HCG1    | HCG-SU-Cart-DAC              | chromatographic immunoassay | CE         |
| 4154HCG1    | HCG-M-Cart-DAC               | chromatographic immunoassay | CE         |
| 4160LH1     | LH-U-Strip-DAC               | chromatographic immunoassay | CE         |
| 4161LH1     | LH-U-Cart-DAC                | chromatographic immunoassay | CE         |
| 4162LH1     | LH-M-Cart-DAC                | chromatographic immunoassay | CE         |
| 4156FSH1    | FSH-U-Strip-DAC              | chromatographic immunoassay | CE         |
| 4157FSH1    | FSH-U-Cart-DAC               | chromatographic immunoassay | CE         |
| 4158FSH1    | FSH-M-Cart-DAC               | chromatographic immunoassay | CE         |
| 4211M1      | Myo-S-Cart-DAC               | chromatographic immunoassay | CE         |
| 4209T1      | Tn I-S-Cart-DAC              | chromatographic immunoassay | CE         |
| 4209TWB1    | Tn I-WB-Cart-DAC             | chromatographic immunoassay | CE         |
| 4221MB1     | CK-MB-S-Cart-DAC             | chromatographic immunoassay | CE         |
| 4219AMI1    | AMI-S-Panel-DAC              | chromatographic immunoassay | CE         |
| 4296N1      | NT-proBNP-Cart-DAC           | chromatographic immunoassay | CE         |
| 4297H1      | H-FABP-Cart-DAC              | chromatographic immunoassay | CE         |
| 4204CEA1    | CEA-S-Strip-DAC              | chromatographic immunoassay | CE         |
| 4205CEA1    | CEA-S-Cart-DAC               | chromatographic immunoassay | CE         |
| 4198AFP1    | AFP-S-Strip-DAC              | chromatographic immunoassay | CE         |
| 4199AFP1    | AFP-S-Cart-DAC               | chromatographic immunoassay | CE         |
| 4201FOB1    | FOB-F-Strip-DAC              | chromatographic immunoassay | CE         |
| 4202FOB1    | FOB-F-Cart-DAC               | chromatographic immunoassay | CE         |
| 4200C1      | CTCC-Cart-DAC                | chromatographic immunoassay | CE         |
| 4232AMP1    | AMP-Strip-DAC                | chromatographic immunoassay | CE         |
| 4233AMP1    | AMP-Cart-DAC                 | chromatographic immunoassay | CE         |
| 4244BAR1    | BAR-Strip-DAC                | chromatographic immunoassay | CE         |
| 4245BAR1    | BAR-Cart-DAC                 | chromatographic immunoassay | CE         |
| 4247BZ01    | BZO-Strip-DAC                | chromatographic immunoassay | CE         |
| 4248BZ01    | BZO-Cart-DAC                 | chromatographic immunoassay | CE         |
| 4226COC1    | COC-Strip-DAC                | chromatographic immunoassay | CE         |
| 4227COC1    | COC-Cart-DAC                 | chromatographic immunoassay | CE         |
| 4258MDMA1   | MDMA-Strip-DAC               | chromatographic immunoassay | CE         |
| 4259MDMA1   | MDMA-Cart-DAC                | chromatographic immunoassay | CE         |
| 4235mAMP1   | mAMP-Strip-DAC               | chromatographic immunoassay | CE         |
| 4236mAMP1   | mAMP-Cart-DAC                | chromatographic immunoassay | CE         |
| 4229MOP1    | MOP-Strip-DAC                | chromatographic immunoassay | CE         |



| Cat. No    | Product                  | Method                      | Cornformity |
|------------|--------------------------|-----------------------------|-------------|
| 4230MOP1   | MOP-Cart-DAC             | chromatographic immunoassay | CE          |
| 4238MTD1   | MTD-Strip-DAC            | chromatographic immunoassay | CE          |
| 4239MTD1   | MTD-Cart-DAC             | chromatographic immunoassay | CE          |
| 4261OPI1   | OPI-Strip-DAC            | chromatographic immunoassay | CE          |
| 4262OPI1   | OPI-Cart-DAC             | chromatographic immunoassay | CE          |
| 4241THC1   | THC-Strip-DAC            | chromatographic immunoassay | CE          |
| 4242THC1   | THC-Cart-DAC             | chromatographic immunoassay | CE          |
| 4264TCA1   | TCA-Strip-DAC            | chromatographic immunoassay | CE          |
| 4265TCA1   | TCA-Cart-DAC             | chromatographic immunoassay | CE          |
| 4267PCP1   | PCP-Strip-DAC            | chromatographic immunoassay | CE          |
| 4268PCP1   | PCP-Cart-DAC             | chromatographic immunoassay | CE          |
| 4253D2     | 2-Drugs-DAC              | chromatographic immunoassay | CE          |
| 4254D3     | 3-Drugs-DAC              | chromatographic immunoassay | CE          |
| 4255D4     | 4-Drugs-DAC              | chromatographic immunoassay | CE          |
| 4256D5     | 5-Drugs-DAC              | chromatographic immunoassay | CE          |
| 4251D6     | 6-Drugs-DAC              | chromatographic immunoassay | CE          |
| 4257D10    | 10-Drugs-DAC             | chromatographic immunoassay | CE          |
| 4252D12    | 12-Drugs-DAC             | chromatographic immunoassay | CE          |
| 4216A1     | Alcohol-Strip-DAC        | chromatographic immunoassay | CE          |
| 4203A1     | Alcohol-U-Strip-DAC      | chromatographic immunoassay | CE          |
| 4270CRP1   | CRP-Cart-DAC             | chromatographic immunoassay | CE          |
| 4272IgE1   | IgE-S-Cart-DAC           | chromatographic immunoassay | CE          |
| 4283AU1    | Albumin Urine-Cart-DAC   | chromatographic immunoassay | CE          |
| 4284hsCRP1 | hsCRP-Cart-DAC           | chromatographic immunoassay | CE          |
| 4285DD1    | D-Dimer-Cart-DAC         | chromatographic immunoassay | CE          |
| 4286RF1    | RF- S-WB-Cart-DAC        | chromatographic immunoassay | CE          |
| 4287NTSH1  | Neonatal TSH-WB-Cart-DAC | chromatographic immunoassay | CE          |
| 4288TSH1   | TSH-S-WB-Cart-DAC        | chromatographic immunoassay | CE          |
| 4289F1     | Ferritin-WB-S-Cart-DAC   | chromatographic immunoassay | CE          |
| 4294P1     | Procalcitonin-Cart-DAC   | chromatographic immunoassay | CE          |
| 4295IG1    | IGFBP-1-Cart-DAC         | chromatographic immunoassay | CE          |





| Cat. No   | Product          | Method                          | Cornformity |
|-----------|------------------|---------------------------------|-------------|
| 1033C100  | CRP-Latex        | Slide agglunation               | CE          |
| 1033C200  | CRP-Latex        | Slide agglunation               | CE          |
| 1033C250  | CRP-Latex        | Slide agglunation               | CE          |
| 1033C500  | CRP-Latex        | Slide agglunation               | CE          |
| 1031A100  | ASLO-DAC         | Slide agglunation               | CE          |
| 1031A200  | ASLO-DAC         | Slide agglunation               | CE          |
| 1031A250  | ASLO-DAC         | Slide agglunation               | CE          |
| 1031A500  | ASLO-DAC         | Slide agglunation               | CE          |
| 1039R100  | RefaTex-DAC      | Slide agglunation               | CE          |
| 1039R200  | RefaTex-DAC      | Slide agglunation               | CE          |
| 1039R250  | RefaTex-DAC      | Slide agglunation               | CE          |
| 1039R500  | RefaTex-DAC      | Slide agglunation               | CE          |
| 1038R200  | RefaTex-conf     | Slide agglunation               | CE          |
| 1041R100  | ReumoScreen-DAC  | Slide agglunation               | CE          |
| 1045W100  | Waalser-Rose-DAC | Slide agglunation               | CE          |
| 1035I100  | IM-DAC           | Slide agglunation               | CE          |
| 1040R100  | RPR-Carbon-DAC   | Slide agglunation               | CE          |
| 1040R250  | RPR-Carbon-DAC   | Slide agglunation               | CE          |
| 1040R500  | RPR-Carbon-DAC   | Slide agglunation               | CE          |
| 1040R1000 | RPR-Carbon-DAC   | Slide agglunation               | CE          |
| 1043S100  | SLE-DAC          | Slide agglunation               | CE          |
| 1044T100  | TPHA-DAC         | Microplate agglutination        | CE          |
| 1044T200  | TPHA-DAC         | Microplate agglutination        | CE          |
| 1047C100  | Candida-Latex    | Slide agglunation               | CE          |
| 1049T100  | Trihomono-Latex  | Slide agglunation               | CE          |
| 1051D50   | D-dimer-DAC      | Slide agglunation               | CE          |
| 1054A50   | AntiSperm-Latex  | Slide agglunation               | CE          |
| 1053A50   | AntiOvary-Latex  | Slide agglunation               | CE          |
| 1032C435  | CIC-DAC          | End point                       | CE          |
| 1036N305  | NBT-DAC          | End point                       | CE          |
| 4051G100  | DAC-1G           | Paper-thin layer chromatography | CE          |
| 4055K100  | DAC-1K           | Paper-thin layer chromatography | CE          |
| 4057B100  | DAC-1B           | Paper-thin layer chromatography | CE          |
| 4059P100  | DAC-1P           | Paper-thin layer chromatography | CE          |
| 4070CM50  | DAC-2CM          | Paper-thin layer chromatography | CE          |
| 4070CM100 | DAC-2CM          | Paper-thin layer chromatography | CE          |
| 4066GK100 | DAC-2GK          | Paper-thin layer chromatography | CE          |
| 4068GP100 | DAC-2GP          | Paper-thin layer chromatography | CE          |
| 4076P100  | DAC-3            | Paper-thin layer chromatography | CE          |
| 4083B100  | DAC-4B           | Paper-thin layer chromatography | CE          |
| 4087S100  | DAC-4S           | Paper-thin layer chromatography | CE          |
| 4091D100  | DAC-5            | Paper-thin layer chromatography | CE          |
| 4101D100  | DAC-7            | Paper-thin layer chromatography | CE          |
| 4103N100  | DAC-8            | Paper-thin layer chromatography | CE          |
| 4113D100  | DAC-9            | Paper-thin layer chromatography | CE          |
| 4117D100  | DAC-10           | Paper-thin layer chromatography | CE          |
| 4121D100  | DAC-11           | Paper-thin layer chromatography | CE          |
| 4124D50   | DAC-12           | Paper-thin layer chromatography | CE          |
| 4124D100  | DAC-12           | Paper-thin layer chromatography | CE          |
| 4062UC24  | UreControl-DAC   | Paper-thin layer chromatography | CE          |

