Declaration of EC-Conformity

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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 **listed in Annex I-III**

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 26.02.2024

Specialist of Normative-Technical Documentation and Certification Department

Anghelova Ana

26.02.2024

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Annex I

Declaration of Conformity according to Regulation (EU) 2017/746 of the European Parliament and of the of 5 April 2017 on in vitro diagnostic medical devices

Product/Trade Name	Catalogue Number	Intended Purpose
ACP-DAC	2002A45	Reagent kit for clinical analysis
Albu-DAC.Lq	3002A50	Reagent kit for clinical analysis
Albu-DAC.Lq	3002A90	Reagent kit for clinical analysis
Albu-DAC.Lq	3002A125	Reagent kit for clinical analysis
Albu-DAC.Lq	3002A250	Reagent kit for clinical analysis
Albu-DAC.Lq	3002A600	Reagent kit for clinical analysis
Albu-DAC.Lq	3002A1000	Reagent kit for clinical analysis
Albu-DAC.Lq	3002A5	Reagent kit for clinical analysis
ALP-DAC	2005A100	Reagent kit for clinical analysis
ALP-DEA-DAC	2006A50	Reagent kit for clinical analysis
ALP-DEA-DAC	2006A100	Reagent kit for clinical analysis
ALP-DEA-DAC	2006A125	Reagent kit for clinical analysis
ALP-DEA-DAC	2006A500	Reagent kit for clinical analysis
ALT-DAC	2008A200	Reagent kit for clinical analysis
ALT-DAC	2008A600	Reagent kit for clinical analysis
ALT-DAC	2008A1200	Reagent kit for clinical analysis
ALT-UV-DAC.Lq	2010A60	Reagent kit for clinical analysis
ALT-UV-DAC.Lq	2010A75	Reagent kit for clinical analysis
ALT-UV-DAC.Lq	2010A150	Reagent kit for clinical analysis
ALT-UV-DAC.Lq	2010A600	Reagent kit for clinical analysis
ALT-UV-DAC.Lq	2010A1200	Reagent kit for clinical analysis
AST-DAC	2023A200	Reagent kit for clinical analysis
AST-DAC	2023A600	Reagent kit for clinical analysis
AST-DAC	2023A1200	Reagent kit for clinical analysis
AST-UV-DAC.Lq	2025A60	Reagent kit for clinical analysis
AST-UV-DAC.Lq	2025A75	Reagent kit for clinical analysis
AST-UV-DAC.Lq	2025A150	Reagent kit for clinical analysis
AST-UV-DAC.Lq	2025A600	Reagent kit for clinical analysis
AST-UV-DAC.Lq	2025A1200	Reagent kit for clinical analysis
Amylo D-DAC.Lq	2019A30	Reagent kit for clinical analysis
Amylo D-DAC.Lq	2019A100	Reagent kit for clinical analysis
Amylo D-DAC.Lq	2019A120	Reagent kit for clinical analysis
Amylo D-DAC.Lq	2019A500	Reagent kit for clinical analysis
Amylo D-DAC.Lq	2019A600	Reagent kit for clinical analysis
Amylo Pancrea-DAC.Lq	2021A75	Reagent kit for clinical analysis

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Amylo-DAC	2015A200	Reagent kit for clinical analysis
Amylo-DAC.Lq	2017A50	Reagent kit for clinical analysis
Amylo-DAC.Lq	2017A125	Reagent kit for clinical analysis
Amylo-DAC.Lq	2017A600	Reagent kit for clinical analysis
Bili D-DAC.Lq	3004B100	Reagent kit for clinical analysis
Bili D-DAC.Lq	3004B500	Reagent kit for clinical analysis
Bili T-DAC.Lq	3006B100	Reagent kit for clinical analysis
Bili T-DAC.Lq	3006B500	Reagent kit for clinical analysis
Bili DT-DAC.Lq	3005B200	Reagent kit for clinical analysis
Bili DT-DAC.Lq	3005B1000	Reagent kit for clinical analysis
Bili D-DAC-CF	3115B100	Reagent kit for clinical analysis
Bili D-DAC-CF	3115B500	Reagent kit for clinical analysis
Bili T-DAC-CF	3116B100	Reagent kit for clinical analysis
Bili T-DAC-CF	3116B500	Reagent kit for clinical analysis
Bili DT-DAC-CF	3117B200	Reagent kit for clinical analysis
Bili DT-DAC-CF	3117B1000	Reagent kit for clinical analysis
Bili-DAC-CF	3008B500	Reagent kit for clinical analysis
Bili D-DAC-DA	3111B125	Reagent kit for clinical analysis
Bili D-DAC-DA	3111B500	Reagent kit for clinical analysis
Bili T-DAC-DA	3112B125	Reagent kit for clinical analysis
Bili T-DAC-DA	3112B500	Reagent kit for clinical analysis
Bili DT-DAC-DA	3113B250	Reagent kit for clinical analysis
Bili DT-DAC-DA	3113B1000	Reagent kit for clinical analysis
Bili D-DAC-VND	3104B120	Reagent kit for clinical analysis
Bili D-DAC-VND	3104B600	Reagent kit for clinical analysis
Bili T-DAC-VND	3106B120	Reagent kit for clinical analysis
Bili T-DAC-VND	3106B600	Reagent kit for clinical analysis
Bili DT-DAC-VND	3108B240	Reagent kit for clinical analysis
Bili DT-DAC-VND	3108B1200	Reagent kit for clinical analysis
Bili St-DAC	3007B3	Reagent kit for clinical analysis
Calcium Ars-DAC.Lq	3010C100	Reagent kit for clinical analysis
Calcium Ars-DAC.Lq	3010C125	Reagent kit for clinical analysis
Calcium Ars-DAC.Lq	3010C200	Reagent kit for clinical analysis
Calcium Ars-DAC.Lq	3010C450	Reagent kit for clinical analysis
Calcium Ars-DAC.Lq	3010C500	Reagent kit for clinical analysis
Calcium Cr-DAC.Lq	3012C100	Reagent kit for clinical analysis
Calcium Cr-DAC.Lq	3012C250	Reagent kit for clinical analysis
Calcium Cr-DAC.Lq	3012C200	Reagent kit for clinical analysis
Calcium Cr-DAC.Lq	3012C500	Reagent kit for clinical analysis
Calcium Free-DAC.Lq	3014C30	Reagent kit for clinical analysis

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Chlor-DAC.Lq	3016C100	Reagent kit for clinical analysis
Chlor-DAC.Lq	3016C125	Reagent kit for clinical analysis
Chol HDL-PR	3023C5	Reagent kit for clinical analysis
Chol HDL-DAC.Lq	3019C200	Reagent kit for clinical analysis
Chol HDL-Direct.Lq	3020C80	Reagent kit for clinical analysis
Chol LDL-Direct.Lq	3021C80	Reagent kit for clinical analysis
Chol-DAC.Lq	3017C50	Reagent kit for clinical analysis
Chol-DAC.Lq	3017C90	Reagent kit for clinical analysis
Chol-DAC.Lq	3017C100	Reagent kit for clinical analysis
Chol-DAC.Lq	3017C125	Reagent kit for clinical analysis
Chol-DAC.Lq	3017C200	Reagent kit for clinical analysis
Chol-DAC.Lq	3017C250	Reagent kit for clinical analysis
Chol-DAC.Lq	3017C500	Reagent kit for clinical analysis
Chol-DAC.Lq	3017C600	Reagent kit for clinical analysis
Chol-DAC.Lq	3017C1000	Reagent kit for clinical analysis
Chol-DAC.Lq	3017C5	Reagent kit for clinical analysis
Cholin-DAC	2030C60	Reagent kit for clinical analysis
Cholin-DAC	2030C150	Reagent kit for clinical analysis
Citric Acid Sp-DAC	3026C100	Reagent kit for clinical analysis
CK-DAC	2035C60	Reagent kit for clinical analysis
CK-DAC	2035C125	Reagent kit for clinical analysis
CK-DAC	2035C150	Reagent kit for clinical analysis
CK-DAC	2035C500	Reagent kit for clinical analysis
CK-MB-Control serum	2060C2	Reagent kit for clinical analysis
CK-MB-DAC	2037C30	Reagent kit for clinical analysis
CK-MB-DAC	2037C120	Reagent kit for clinical analysis
Copper-DAC.Lq	3028C50	Reagent kit for clinical analysis
Crea Kinetic-DAC.Lq	3035C100	Reagent kit for clinical analysis
Crea Kinetic-DAC.Lq	3035C200	Reagent kit for clinical analysis
Crea Kinetic-DAC.Lq	3035C250	Reagent kit for clinical analysis
Crea Kinetic-DAC.Lq	3035C500	Reagent kit for clinical analysis
Crea Kinetic-DAC.Lq	3035C1000	Reagent kit for clinical analysis
Crea-DAC	3030C260	Reagent kit for clinical analysis
Creatinine Enzym-DAC.Lq	3036C100	Reagent kit for clinical analysis
Fructosamine-DAC	3037F100	Reagent kit for clinical analysis
FructoseSp-DAC.Lq	3033F100	Reagent kit for clinical analysis
GGT-DAC.Lq	2040G50	Reagent kit for clinical analysis
GGT-DAC.Lq	2040G100	Reagent kit for clinical analysis
GGT-DAC.Lq	2040G125	Reagent kit for clinical analysis
GGT-DAC.Lq	2040G200	Reagent kit for clinical analysis

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GGT-DAC.Lq	2040G450	Reagent kit for clinical analysis
GGT-DAC.Lq	2040G500	Reagent kit for clinical analysis
Gluco HK-DAC	3042G200	Reagent kit for clinical analysis
Gluco-cont	3038G5	Reagent kit for clinical analysis
Gluco-DAC.Lq	3044G100	Reagent kit for clinical analysis
Gluco-DAC.Lq	3044G125	Reagent kit for clinical analysis
Gluco-DAC.Lq	3044G200	Reagent kit for clinical analysis
Gluco-DAC.Lq	3044G450	Reagent kit for clinical analysis
Gluco-DAC.Lq	3044G500	Reagent kit for clinical analysis
Gluco-DAC.Lq	3044G600	Reagent kit for clinical analysis
Gluco-DAC.Lq	3044G1000	Reagent kit for clinical analysis
Glyco HbControls	1111GC2	Reagent kit for clinical analysis
GlycoHb-DAC	1105G20	Reagent kit for clinical analysis
GlycoHb-DAC	1105G20x3	Reagent kit for clinical analysis
GlycoHb-DAC	1105G50	Reagent kit for clinical analysis
GlycoHb-DAC	1105G50x3	Reagent kit for clinical analysis
GlycoHbStandard	1108GS1	Reagent kit for clinical analysis
Hb Chr-DAC.Lq	3046H1000	Reagent kit for clinical analysis
Hb Chr-DAC.Lq	3046H3000	Reagent kit for clinical analysis
Helico-DAC	3050H130	Reagent kit for clinical analysis
Homocysteine-DAC.Lq	3070H70	Reagent kit for clinical analysis
Iodine-DAC	3054120	Reagent kit for clinical analysis
Iodine-DAC	3054150	Reagent kit for clinical analysis
Iron Ch-DAC.Lq	30521100	Reagent kit for clinical analysis
Iron Ch-DAC.Lq	30521250	Reagent kit for clinical analysis
Iron-Ferene.DAC.Lq	30551100	Reagent kit for clinical analysis
Iron Ferr-DAC.Lq	30561100	Reagent kit for clinical analysis
LDH-DAC.Lq	2044L50	Reagent kit for clinical analysis
LDH-DAC.Lq	2044L200	Reagent kit for clinical analysis
Lipase-DAC.Lq	2046L75	Reagent kit for clinical analysis
Lithium Enzym-DAC.Lq	3058L60	Reagent kit for clinical analysis
Magne-DAC.Lq Калмагит	3060M100	Reagent kit for clinical analysis
Multi H St -DAC	2053M3	Control kit for clinical analysis
Multi H St -DAC	2053M18	Control kit for clinical analysis
Multi H St -DAC	2053M60	Control kit for clinical analysis
Phosph-DAC.Lq	3064P100	Reagent kit for clinical analysis
Phosph-DAC.Lq	3064P200	Reagent kit for clinical analysis
PhosphoLipid-DAC	3062P50	Reagent kit for clinical analysis
Potassium Enzym-DAC.Lq	3067P50	Reagent kit for clinical analysis
Potassium -DAC.Lq	3066P50	Reagent kit for clinical analysis

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Potassium -DAC.Lq	3066P250	Reagent kit for clinical analysis
Prot Ure-DAC.Lq	3076U50	Reagent kit for clinical analysis
Prot Ure-DAC.Lq	3076U90	Reagent kit for clinical analysis
Prot Ure-DAC.Lq	3076U250	Reagent kit for clinical analysis
Prot Ure-DAC.Lq	3076U5	Reagent kit for clinical analysis
Prote-DAC.Lq	3072P50	Reagent kit for clinical analysis
Prote-DAC.Lq	3072P90	Reagent kit for clinical analysis
Prote-DAC.Lq	3072P125	Reagent kit for clinical analysis
Prote-DAC.Lq	3072P250	Reagent kit for clinical analysis
Prote-DAC.Lq	3072P600	Reagent kit for clinical analysis
Prote-DAC.Lq	3072P1000	Reagent kit for clinical analysis
Prote-DAC.Lq	3072P5	Reagent kit for clinical analysis
Sera hN-DAC	2062S5	Control kit for clinical analysis
Sera hN-DAC	2062S30	Control kit for clinical analysis
Sera hN-DAC	2062S100	Control kit for clinical analysis
Sera hP-DAC	2064S5	Control kit for clinical analysis
Sera hP-DAC	2064S30	Control kit for clinical analysis
Sera hP-DAC	2064S100	Control kit for clinical analysis
Sodium Enzym-DAC	3079S80	Reagent kit for clinical analysis
Sodium-DAC.Lq	3078S50	Reagent kit for clinical analysis
Sodium-DAC.Lq	3078S250	Reagent kit for clinical analysis
Sulfo-DAC	3081S200	Reagent kit for clinical analysis
Sulfo-DAC	3081S5	Reagent kit for clinical analysis
TG-DAC.Lq	3085T50	Reagent kit for clinical analysis
TG-DAC.Lq	3085T90	Reagent kit for clinical analysis
TG-DAC.Lq	3085T125	Reagent kit for clinical analysis
TG-DAC.Lq	3085T250	Reagent kit for clinical analysis
TG-DAC.Lq	3085T600	Reagent kit for clinical analysis
TG-DAC.Lq	3085T1000	Reagent kit for clinical analysis
Thymol DAC	3087T500	Reagent kit for clinical analysis
Thymol DAC	3087T1500	Reagent kit for clinical analysis
Thymol DAC	3087T1500St	Reagent kit for clinical analysis
Thymol DAC-Standard	3088T15	Reagent kit for clinical analysis
Thymol DAC-Standard	3088T125	Reagent kit for clinical analysis
TIBC-DAC	3083T120	Reagent kit for clinical analysis
Total Lipids-DAC.Lq	3086T100	Reagent kit for clinical analysis
Ure UV-DAC.Lq	3094U60	Reagent kit for clinical analysis
Ure UV-DAC.Lq	3094U100	Reagent kit for clinical analysis
Ure UV-DAC.Lq	3094U500	Reagent kit for clinical analysis
Ure UV-DAC.Lq	3094U1000	Reagent kit for clinical analysis

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LL: DACI	200211402	December 19 1 1 1 1
Ure-DAC.Lq	3092U100	Reagent kit for clinical analysis
Ure-DAC.Lq	3092U180	Reagent kit for clinical analysis
Ure-DAC.Lq	3092U200	Reagent kit for clinical analysis
Ure-DAC.Lq	3092U500	Reagent kit for clinical analysis
Ure-DAC.Lq	3092U1000	Reagent kit for clinical analysis
Uric Acid-DAC.Lq	3096U50	Reagent kit for clinical analysis
Uric Acid-DAC.Lq	3096U100	Reagent kit for clinical analysis
Uric Acid-DAC.Lq	3096U200	Reagent kit for clinical analysis
Uric Acid-DAC.Lq	3096U500	Reagent kit for clinical analysis
Uric Acid-DAC.Lq	3096U1000	Reagent kit for clinical analysis
Zinc Sp-DAC.Lq	3101Z50	Reagent kit for clinical analysis
Zinc-DAC.Lq	3102Z50	Reagent kit for clinical analysis
Alcohol-DAC	3121A75	Reagent kit for clinical analysis
Alcohol-DAC	3121A150	Reagent kit for clinical analysis
Control Ca Free-DAC.Lq	3013C20	Reagent kit for clinical analysis
APTT-DAC-EA	4005A25	Reagent kit for hemostasis evaluation
APTT-DAC-EA	4005A50	Reagent kit for hemostasis evaluation
APTT-DAC-EA	4005A160	Reagent kit for hemostasis evaluation
APTT-DAC-EA	4005A100	Reagent kit for hemostasis evaluation
APTT-DAC-EA	4005A200	Reagent kit for hemostasis evaluation
Calcium Chloride-DAC	4024C64	Reagent kit for hemostasis evaluation
Coagulo-cont N	4006C2	Control kit for hemostasis evaluation
Coagulo-cont N	4006C3	Control kit for hemostasis evaluation
Coagulo-cont N	4006C10	Control kit for hemostasis evaluation
Coagulo-cont P	4007C2	Control kit for hemostasis evaluation
Coagulo-cont P	4007C3	Control kit for hemostasis evaluation
Coagulo-cont P	4007C10	Control kit for hemostasis evaluation
Coagulo-cont P+	4030C2	Control kit for hemostasis evaluation
Coagulo St-DAC	4018C1	Control kit for hemostasis evaluation
Coagulo St-DAC	4018C10	Control kit for hemostasis evaluation
Control Plasma L1	4032C2	Control kit for hemostasis evaluation
Control Plasma L1+L2	4032C4	Control kit for hemostasis evaluation
Control Plasma L2	4033C2	Control kit for hemostasis evaluation
Control Plasma L2+	4034C2	Control kit for hemostasis evaluation
Fibrinogen-DAC	4020F60	Reagent kit for hemostasis evaluation
Fibrinogen-DAC	4020F120	Reagent kit for hemostasis evaluation
Fibrinogen-DAC	4020F160	Reagent kit for hemostasis evaluation
Fibrinogen-DAC	4020F400	Reagent kit for hemostasis evaluation
Haemostaz-DAC-I	4008H350	Reagent kit for hemostasis evaluation
Haemostaz-DAC-II	4010H100	Reagent kit for hemostasis evaluation

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Haemostaz-DAC-II	4010H50	Reagent kit for hemostasis evaluation
Imidazol-DAC	4022160	Reagent kit for hemostasis evaluation
Prothrombin-DAC-mono ISI	4011P80	Reagent kit for hemostasis evaluation
Prothrombin-DAC-mono ISI	4011P200	Reagent kit for hemostasis evaluation
Prothrombin-DAC-mono ISI	4011P4x10	Reagent kit for hemostasis evaluation
Prothrombin-DAC-mono ISI	4011P500	Reagent kit for hemostasis evaluation
Prothrombin-DAC.Lq ISI	4013P25	Reagent kit for hemostasis evaluation
Prothrombin-DAC.Lq ISI	4013P50	Reagent kit for hemostasis evaluation
Prothrombin-DAC.Lq ISI	4013P100	Reagent kit for hemostasis evaluation
Prothrombin-DAC.Lq ISI	4013P200	Reagent kit for hemostasis evaluation
Prothrombin-DAC-ISI	4012P100	Reagent kit for hemostasis evaluation
Prothrombin-DAC-ISI	4012P240	Reagent kit for hemostasis evaluation
Prothrombin-DAC-ISI	4012P300	Reagent kit for hemostasis evaluation
Thrombin-DAC-mono	4015T120	Reagent kit for hemostasis evaluation
Thrombin-DAC-mono	4015T300	Reagent kit for hemostasis evaluation
Anti-Zona Pellucida-Latex	1052A50	Reagent kit for latex agglutination tests
ASLO-DAC	1031A100	Reagent kit for latex agglutination tests
ASLO-DAC	1031A200	Reagent kit for latex agglutination tests
ASLO-DAC	1031A250	Reagent kit for latex agglutination tests
ASLO-DAC	1031A500	Reagent kit for latex agglutination tests
Candida-Latex	1047C100	Reagent kit for latex agglutination tests
CIC-DAC	1032C218	Reagent kit for latex agglutination tests
CIC-DAC	1032C435	Reagent kit for latex agglutination tests
CRP-Latex	1033C50	Reagent kit for latex agglutination tests
CRP-Latex	1033C100	Reagent kit for latex agglutination tests
CRP-Latex	1033C200	Reagent kit for latex agglutination tests
CRP-Latex	1033C250	Reagent kit for latex agglutination tests
CRP-Latex	1033C500	Reagent kit for latex agglutination tests
D-dimer-DAC	1051D50	Reagent kit for latex agglutination tests
IM-DAC	10351100	Reagent kit for latex agglutination tests
IM-DAC	10351250	Reagent kit for latex agglutination tests
IM-DAC	10351500	Reagent kit for latex agglutination tests
NBT-DAC	1036N305	Reagent kit for latex agglutination tests
RefaTex-DAC	1039R100	Reagent kit for latex agglutination tests
RefaTex-DAC	1039R200	Reagent kit for latex agglutination tests
RefaTex-DAC	1039R250	Reagent kit for latex agglutination tests
RefaTex-DAC	1039R500	Reagent kit for latex agglutination tests
ReumoScreen-DAC	1041R100	Reagent kit for latex agglutination tests
ReumoScreen-DAC	1041R250	Reagent kit for latex agglutination tests
ReumoScreen-DAC	1041R500	Reagent kit for latex agglutination tests

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RPR-Carbon-DAC	1040R100	Reagent kit for agglutination tests
RPR-Carbon-DAC	1040R100P	Reagent kit for agglutination tests
RPR-Carbon-DAC	1040R250	Reagent kit for agglutination tests
RPR-Carbon-DAC	1040R200D	Reagent kit for agglutination tests
RPR-Carbon-DAC	1040R250D	Reagent kit for agglutination tests
RPR-Carbon-DAC	1040R500	Reagent kit for agglutination tests
RPR-Carbon-DAC	1040R500D	Reagent kit for agglutination tests
RPR-Carbon-DAC	1040R1000	Reagent kit for agglutination tests
SLE-DAC	1043S100	Reagent kit for latex agglutination tests
SLE-DAC	1043S250	Reagent kit for latex agglutination tests
SLE-DAC	1043S500	Reagent kit for latex agglutination tests
Toxo-Latex	1046T100	Reagent kit for latex agglutination tests
TPHA-DAC	1044T100	Reagent kit for hemagglutination tests
TPHA-DAC	1044T200	Reagent kit for hemagglutination tests
Trichomono-Latex	1049T100	Reagent kit for hemagglutination tests
Waaler-Rose-DAC	1045W100	Reagent kit for hemagglutination tests
Waaler-Rose-DAC	1045W250	Reagent kit for hemagglutination tests
Waaler-Rose-DAC	1045W500	Reagent kit for hemagglutination tests
α ₁ -Glycoprotein Acid-DAC	1203G50	Reagent kit for clinical analysis turbidimetric
α ₁ -Antitrypsin-DAC	1178A50	Reagent kit for clinical analysis turbidimetric
Apolipoprotein A1-DAC	1174A50	Reagent kit for clinical analysis turbidimetric
Apolipoprotein B-DAC	1176A50	Reagent kit for clinical analysis turbidimetric
ASLO-Turbilatex	1135A50	Reagent kit for clinical analysis turbidimetric
Calibrator Apo A1/B-DAC	1195C1	Reagent kit for clinical analysis turbidimetric
Ceruloplasmin-DAC	1162C50	Reagent kit for clinical analysis turbidimetric
Complement C3-DAC	1166C50	Reagent kit for clinical analysis turbidimetric
Complement C4-DAC	1168C50	Reagent kit for clinical analysis turbidimetric
Control Apo A1/B-DAC	1197C1	Reagent kit for clinical analysis turbidimetric
Control ASLO/CRP/RF-DAC Level H	1152C1	Reagent kit for clinical analysis turbidimetric
Control ASLO/CRP/RF-DAC Level L	1151C1	Reagent kit for clinical analysis turbidimetric
Control Ferritin-DAC	1148C2	Reagent kit for clinical analysis turbidimetric
Control β ₂ -Microglobulin-DAC	1140C2	Reagent kit for clinical analysis turbidimetric
CRP-Turbilatex	1150C50	Reagent kit for clinical analysis turbidimetric
CRP-ultra Turbilatex	1201CU50	Reagent kit for clinical analysis turbidimetric
Ferritin-DAC	1144F50	Reagent kit for clinical analysis turbidimetric
Haptoglobin-DAC	1191H50	Reagent kit for clinical analysis turbidimetric
HbA1c Calibrator (4 levels)	1103H2	Reagent kit for clinical analysis turbidimetric
HbA1c Control (2 levels)	1104H4	Reagent kit for clinical analysis turbidimetric
HbA1c-Turbi-DAC	1102H75	Reagent kit for clinical analysis turbidimetric
HbA1c-Turbi-DAC	1102H180	Reagent kit for clinical analysis turbidimetric

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IgA Turbi-DAC	1156IA50	Reagent kit for clinical analysis turbidimetric
IgE Turbi-DAC	1161IE30	Reagent kit for clinical analysis turbidimetric
IgG Turbi-DAC	1158IG50	Reagent kit for clinical analysis turbidimetric
IgM Turbi-DAC	1160IM50	Reagent kit for clinical analysis turbidimetric
β ₂ -Microglobulin-DAC	1141M50	Reagent kit for clinical analysis turbidimetric
Protein Sera-DAC	1172P1	Reagent kit for clinical analysis turbidimetric
Protein Sera-DAC	1172P2	Reagent kit for clinical analysis turbidimetric
Protein Sera-DAC	1172P4	Reagent kit for clinical analysis turbidimetric
Protein St-DAC	1170P2	Reagent kit for clinical analysis turbidimetric
RF-Turbilatex	1129R50	Reagent kit for clinical analysis turbidimetric
Transferrin-DAC	1164T50	Reagent kit for clinical analysis turbidimetric

Annex II

Declaration of Conformity according to Regulation (EU) 2017/746 of the European Parliament and of the of 5 April 2017 on in vitro diagnostic medical devices

Product/Trade Name	Catalogue Number	Intended Purpose
DAC-1G	4051G100	Reagent strips for urinalysis
DAC-1B	4057B100	Reagent strips for urinalysis
DAC-1K	4055K50	Reagent strips for urinalysis
DAC-1K	4055K100	Reagent strips for urinalysis
DAC-1P	4059P100	Reagent strips for urinalysis
DAC-2CM	4070CM100	Reagent strips for urinalysis
DAC-2CM	4070CM50	Reagent strips for urinalysis
DAC-2GK	4066GK100	Reagent strips for urinalysis
DAC-2GP	4068GP100	Reagent strips for urinalysis
DAC-3	4076D100	Reagent strips for urinalysis
DAC-4	4089D100	Reagent strips for urinalysis
DAC-4B	4083D100	Reagent strips for urinalysis
DAC-4S	4087D100	Reagent strips for urinalysis
DAC-5	4091D100	Reagent strips for urinalysis
DAC-6	4094D100	Reagent strips for urinalysis
DAC-7	4101D100	Reagent strips for urinalysis
DAC-8	4103N100	Reagent strips for urinalysis
DAC-9	4113D100	Reagent strips for urinalysis
DAC-10	4117D100	Reagent strips for urinalysis
DAC-11	4121D100	Reagent strips for urinalysis
DAC-12	4124D100	Reagent strips for urinalysis
DAC-12	4124D50	Reagent strips for urinalysis
DAC-13	4125D100	Reagent strips for urinalysis

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UriControl-DAC	4062UC16	Control kit for urinalysis
UriControl-DAC	4062UC10	Control kit for urinalysis

Annex III

Declaration of Conformity according to Regulation (EU) 2017/746 of the European Parliament and of the of 5 April 2017 on in vitro diagnostic medical devices

Product/Trade Name	Catalogue Number	Intended Purpose
Adeno-Rota-Cart-DAC	4279AR1	Medical devices for rapid tests
HP-Cart-DAC	4215HP1	Medical devices for rapid tests
HP-F-Cart-DAC	4250HP1	Medical devices for rapid tests
Influenza A/B 2-Panel-DAC	4282IAB1	Medical devices for rapid tests
Malaria P.f /P.vAb-Cart-DAC	4217M1	Medical devices for rapid tests
Mononucleosis-S-WB-Cart-DAC	4281M1	Medical devices for rapid tests
Streptococ A-Cart-DAC	4214SA1	Medical devices for rapid tests
Strep B-Cart-DAC	4276SB1	Medical devices for rapid tests
AMI-S-Panel-DAC	4219AMI1	Medical devices for rapid tests
CK-MB-S-Cart-DAC	4221MB1	Medical devices for rapid tests
Myo-S-Cart-DAC	4211M1	Medical devices for rapid tests
Tn I-WB-Cart-DAC	4209TWB1	Medical devices for rapid tests
6-Drugs-DAC	4251D6	Medical devices for rapid tests
10-Drugs-DAC	4257D10	Medical devices for rapid tests
AFP-S-Cart-DAC	4199AFP1	Medical devices for rapid tests
CEA-S-Strip-DAC	4204CEA1	Medical devices for rapid tests
FOB-F-Cart-DAC	4202FOB1	Medical devices for rapid tests
FOB-F-Strip-DAC	4201FOB1	Medical devices for rapid tests
Albumin Urine-Cart-DAC	4283AU1	Medical devices for rapid tests
CRP-Cart-DAC	4270CRP1	Medical devices for rapid tests
D-Dimer-Cart-DAC	4285DD1	Medical devices for rapid tests
IGFBP-1-Cart-DAC	4295IG	Medical devices for rapid tests
Procalcitonin-Cart-DAC	4294P1	Medical devices for rapid tests
RF-S-WB-Cart-DAC	4286RF1	Medical devices for rapid tests