

CEDENTE:



FAR S.r.l.

Via Fermi, 12
37026 SETTIMO DI PESCONTINA - VERONA - ITALY
Tel. N.: +39 045 6700870 / +39 045 6700871
Fax N.: +39 045 7157763

web site: <http://www.fardiag.com>
e-mail: fardiag@fardiag.com

Partita IVA: 00874640238

EC DECLARATION OF CONFORMITY

The undersigner Dr. Renzo Ronca, in his capacity of general manager of FAR srl, located in Via Fermi, 12 - 37026 Pescantina (Verona - ITALY),

DECLARES

upon his honour, that the following products:

CODE	PRODUCT	KIT SIZE
CL01-100	ACE	4x25 ml
CL04-200S	Albumin Mono+Std	2x100 ml + S
CL04-400S	Albumin Mono+Std	4x100 ml + S
CL28-125S	Alcohol (Ethanol) 4+1+Std	4x25 ml + 1x25 ml + S
CL32-100	Alk. Phosph. DGKC 4+1	2x40 ml + 2x10 ml
CL32-200	Alk. Phosph. DGKC 4+1	2x80 ml + 2x20 ml
CL05-60	Amylase CNPG3 Mono	6x10 ml
CL05-150	Amylase CNPG3 Mono	6x25 ml
CL07-125S	Bicarbonate Mono+Std	5x25 ml + S
CL14-200S	Calcium ARS Mono+Std	4x50 ml + S
CL14-400S	Calcium ARS Mono+Std	4x100 ml + S
CL16-125S	Calcium OCP 4+1+Std	1x100 ml + 1x25 ml + S
CL20-200S	Chlorides Mono+Std	2x100 ml + S
CL22-160	Cholesterol HDL 3+1	2x60 ml + 2x20 ml
CL24-160	Cholesterol LDL 3+1	2x60 ml + 2x20 ml
CL21-200S	Cholesterol Mono+Std	4x50 ml + S
CL21-400S	Cholesterol Mono+Std	4x100 ml + S
CL25-120	Cholinesterase 5+1	2x50 ml + 2x10 ml
CL18-75	CK MB 4+1	2x30 ml + 2x7.5 ml
CL19-75	CK NAC 4+1	2x30 ml + 2x7.5 ml
CL52-120S	Copper 4+1+Std	4x25 ml + 2x10 ml + S
CL26-200S	Creatinine JAF 1+1+Std	2x50 ml + 2x50 ml + S
CL26-400S	Creatinine JAF 1+1+Std	2x100 ml + 2x100 ml + S
CL57-125S	Creatinine JAF 4+1+Std	2x50 ml + 1x25 ml + S
CL57-250S	Creatinine JAF 4+1+Std	2x100 ml + 2x25 ml + S

Declaration of Conformity drawn up according to UNI CEI EN 45014 "General criteria for supplier's declaration of conformity".

CL09-250	Direct Bilirubin DPD 4+1	2x100 ml + 2x25 ml
CL08-110	Direct Bilirubin JEN 10+1	1x100 ml + 1x10 ml
CL12-220	D+T Bilirubin JEN 10+1	1x100 ml + 1x100 ml + 2x10 ml
CL34-100	Gamma GT 4+1	2x40 ml + 2x10 ml
CL34-200	Gamma GT 4+1	2x80 ml + 2x20 ml
CL35-200S	Glucose Mono+Std	4x50 ml + S
CL35-400S	Glucose Mono+Std	4x100 ml + S
CL36-275	GOT/AST 10+1	5x50 ml + 1x25 ml
CL37-200	GOT/AST 4+1	4x40 ml + 4x10 ml
CL37-375	GOT/AST 4+1	3x100 ml + 1x75 ml
CL38-275	GPT/ALT 10+1	5x50 ml + 1x25 ml
CL39-200	GPT/ALT 4+1	4x40 ml + 4x10 ml
CL39-375	GPT/ALT 4+1	3x100 ml + 1x75 ml
CL30-250S	Iron FER 4+1+Std	2x100 ml + 2x25 ml + S
CL31-250S	Iron FZN 4+1+Std	2x100 ml + 2x25 ml + S
CL56-125S	Lactate Mono+Std	5x25 ml + S
CL41-275	LDH 10+1	5x50 ml + 1x25 ml
CL42-100	LDH 4+1	2x40 ml + 2x10 ml
CL43-160S	Lipase 5+3+Std	2x50 ml + 2x30 ml + S
CL47-100S	Magnesium XIL Mono+Std	4x25 ml + S
CL47-200S	Magnesium XIL Mono+Std	2x100 ml + S
CL40-125	Pancreatic Am. EPS 4+1	4x25 ml + 1x25 ml
CL33-200S	Phosphorus Mono+Std	2x100 ml + S
CL50-200S	Proteins Mono+Std	4x50 ml + S
CL51-200S	Proteins Mono+Std	2x100 ml + S
CL11-250	Total Bilirubin DPD 4+1+Std	2x100 ml + 2x25 ml
CL10-330	Total Bilirubin JEN 10+1	3x100 ml + 3x10 ml
CL49-200S	Total Proteins Mono+Std	2x100 ml + S
CL49-400S	Total Proteins Mono+Std	4x100 ml + S
CL53-200S	Triglycerides Mono+Std	4x50 ml + S
CL53-400S	Triglycerides Mono+Std	4x100 ml + S
CL54-200	Urea UV 4+1+Std	4x40 ml + 4x10 ml
CL02-200S	Uric acid Mono+Std	4x50 ml + S
CL02-400S	Uric acid Mono+Std	4x100 ml + S
CL55-100S	Zinc 4+1+Std	2x40 ml + 2x10 ml + S
CY01-72	AAP	12x6
CY02-36	ACE	9x4
CY03-100	Citric Acid	5x20
CY04-55	Ammonia	22x2,5
CP01-50	Alcohol (Ethanol)	5x10
CP02-30	Acid Phosphatase	10x3
CY05-75	Phospholipids	3x25
CP03-120	Fructosamine	4x30
CY06-100	G 6 PDH	4x25
CY07-72	Lisozyme	12x6
CY07-150	Lisozyme	10x15

CY08-40T	NAG	4x10 test
CY09-72	Potassium	4x12,5+2x11
CY10-80	Sodium	4x15+2x10
CP04-133	Copper Serum	5x25+1x8
CP05-125	Copper Urine	3x25+2x25
CP06-200	Urea Color	2x100
CP07-100	Zinc	4x25
CM03-50T	ALA Dehydrase	50 test
CM06-25	Carboxyhemoglobin	5x5
CM01-100T	Hippuric Acid	100 test
CM08-30T	Hydroxyproline New	10x3 test
CM05-50T	Kidney Stones	50 test
CM10-25T	Methemoglobin	25 test
CM07-50T	Phenols	50 test
CM11-100	TIBC	4x25
CM09-400	Total Lipids	4x100
CM02-100T	Trichloroacetic Acid	100 test
CM12-60T	Xylose	60 test
CM13-100T	Xylose Urine	100 test
7506	AAP/NAG Standard	1x1 ml
7512	ACE Calibrator	1x2 ml
7508	ACE Controlserum N+P	2x1 ml
7514	Albumin Standard	1x5 ml
7520	Ammonia Standard	1x5 ml
7510	Fructosamine Controlserum N+P	2x1 ml
7516	Glucose Standard	1x5 ml
7522	Lysozyme Control L1+L2	2x1 ml
7500	Lysozyme Standard	1x1 ml
7502	Potassium Standard	2x5x1 ml
7518	Total Protein Standard	1x5 ml
7504	Sodium Standard	2x5x1 ml
7532	Calibrator Clinical Chemistry	10x3 ml
7526	Pre-norm (Precision Normal Serum)	5x5 ml
7528	Pre-path (Precision Pathological Serum)	5x5 ml
KR01-20	ALA	20 test
KR02-10	ALA - PBG	10+10 test
KR03-20	Ammonia	20 test
KR04-20	17 Ketosteroids	20 test
KR05-20	Haemoglobin A1c	20 test
KR06-20	Haemoglobin A2	20 test
KR07-20	5 HIAA	20 test
KR08-20	Metanephrines	20 test
KR09-20	Porphyryns	20 test
KR10-20	Proto Porphyryns	20 test
KR11-20	U/C Porphyryns	20 test
KR12-20	Vanillylmandelic Acid	20 test
KR13-40	Haemoglobin A1	40 test

KR13-96	Haemoglobin A1	96 test
3643	Hemoglobin A2 control P	1x0,5 ml
3659	Glycated Hemoglobin A1c control N	1x0,5 ml
3660	Glycated Hemoglobin A1c control P	1x0,5 ml
3649	Control Urine	10x10 ml
RD01-12	IgA	12
RD02-12	IgG	12
RD03-12	IgM	12
RD04-12	C3c	12
RD05-12	C4	12
RD06-12	Ig/Chains k	12
RD07-12	Ig/Chains l	12
RD08-12	Transferrin	12
RD09-12	Antithrombin III	12
RD41-12	IgA+IgG+IgM	4+4+4
RD42-08	C3c+C4	4+4
RD43-08	Ig/Chains k + Ig/Chains l	4+4
RD20-01	Multiparametric Calibrator	1x1 ml
4057	Rotavirus card	20 test
4058	Duo Rota-Adenovirus card	20 test
4009	Chlamy-CHECK-1	20 tests
4062	Helicobacter Pylori card in faeces	20 tests
4011	Strep A card	20 tests
4012	Strep B card	20 tests
4005	Occult Blood card	20 tests
4025	Occult Blood card	50 tests
4052	Occult Blood card	100 tests
4020	Occult Blood collection device	100 pcs
4046	Troponin I card	20 tests
4003	hCG card	20 tests
4024	hCG card	50 tests
4051	hCG card	100 tests
4041	Microalbumine card	20 tests
6200	Salmonella Typhi H	3x10 ml
6201	Salmonella Typhi O	3x10 ml
6205	Salmonella Paratyphi A Totale	3x10 ml
6208	Salmonella Paratyphi B Totale	3x10 ml
6215	Brucella Total/Abortus	3x10 ml
6216	Proteus OX 19	3x10 ml
6217	Proteus OX 2	3x10 ml
6218	Proteus OX K	3x10 ml
6220	Multiple micro 3	3x10 ml
6225	Multiple micro 5	5x10 ml
6219	Multiple micro 7	7x10 ml
6300	Salmonella Typhi H	2x20 ml
6301	Salmonella Typhi O	2x20 ml
6302	Salmonella Typhi Totale	2x20 ml

6305	Salmonella Paratyphi A Totale	2x10 ml
6308	Salmonella Paratyphi B Totale	2x10 ml
6315	Brucella Total/Abortus	2x20 ml
6321	Multiple macro 3	3x20 ml
6320	Multiple macro 5	5x20 ml
6400	Salmonella Typhi H	100 tests
6401	Salmonella Typhi O	100 tests
6402	Salmonella Paratyphi AH	100 tests
6403	Salmonella Paratyphi AO	100 tests
6418	Salmonella Paratyphi A Totale	100 tests
6404	Salmonella Paratyphi BH	100 tests
6405	Salmonella Paratyphi BO	100 tests
6419	Salmonella Paratyphi B Totale	100 tests
6408	Brucella Total/Abortus	100 tests
6410	Proteus OX 19	100 tests
6411	Proteus OX 2	100 tests
6412	Proteus OX K	100 tests
6415	Multiple slide 3	3x100 tests
6413	Multiple slide 7	7x100 tests
6500	Multipurpose Control Pos+Neg	4x1 ml
6000	ASO latex kit	100 tests
6100	ASO latex	2x5 ml
6001	PCR latex kit	100 tests
6101	PCR latex	2x5 ml
6002	RF latex kit	100 tests
6102	RF latex	2x5 ml
6003	Waler-Rose ema kit	100 tests
6005	Mononucleosis ema kit	100 tests
6006	RPR carbon kit	100 tests
6009	TPHA kit	96 tests
4555	C3c	2x10 ml + 2x1 ml
4556	C4	2x10 ml + 2x1 ml
4560	k CHAINS free and bound	2x10 ml + 2x1 ml
4561	λ CHAINS free and bound	2x10 ml + 2x1 ml
4557	IgA	2x10 ml + 2x1 ml
4558	IgG	2x10 ml + 2x1 ml
4559	IgM	2x10 ml + 2x1 ml
4554	Protein C Reactive	2x10 ml + 2x1 ml
4563	TRANSFERRIN	2x10 ml + 2x1 ml
4600	CRP Calibrator	1x0,5 ml
4601	K and λ chain Calibrator	1x0,5 ml
4602	Plasmaprotein Calibrator	1x1 ml
3089	α-Naphtyl Acetate Est. Leuk.	10x4 tests
3091	α-Naphtyl Butyrate Est. Leuk.	10x4 tests
3092	Naphtol AS-D Chloroac. Est. Leuk.	10x4 tests
3093	Acid Phosphatase Leukocyte	10x4 tests
3094	Alkaline Phosphatase Leukocyte	10x4 tests

3090	Peroxydase Leukocyte	10x4 tests
3081	PAS	10x4 tests
3098	PERLS	10x4 tests
3099	SUDAN BLACK B	10x4 tests
EM01-100	CPT	100 pcs
2128	Reticulocyte counts kit	50 pcs
BT01-60	ACE Mono	3x20 mL
BT04-100	Albumin Mono	2x50 mL
BT28-100	Alcohol (Ethanol) 4+1	2x40 + 2x10 mL
BT32-150	Alkaline Phosphatase DGKC 4+1	3x40 + 3x10 mL
BT05-60	Amylase CNPG3 Mono	3x20 mL
BT07-60	Bicarbonate Mono	3x20 mL
BT08-125	Direct Bilirubin JEN 4+1	2x50 + 2x12,5 mL
BT09-125	Direct Bilirubin DPD 4+1	2x50 + 2x12,5 mL
BT10-250	Total Bilirubin JEN 4+1	4x50 + 4x12,5 mL
BT11-250	Total Bilirubin DPD 4+1	4x50 + 4x12,5 mL
BT14-100	Calcium ARS Mono	2x50 mL
BT16-125	Calcium OCP 4+1	2x50 + 2x12,5 mL
BT20-100	Chlorides Mono	2x50 mL
BT21-200	Cholesterol Mono	4x50 mL
BT22-180	Cholesterol HDL 3+1	3x45 + 3x15 mL
BT24-120	Cholesterol LDL 3+1	2x45 + 2x15 mL
BT25-120	Cholinesterase 5+1	2x50 + 2x10 mL
BT18-60	CK MB 4+1	1x48 + 1x12 mL
BT19-125	CK NAC 4+1	2x50 + 2x12,5 mL
BT52-50	Copper 4+1	2x20 + 2x5 mL
BT57-250	Creatinine JAF 4+1	4x50 + 4x12,5 mL
BT34-150	Gamma GT 4+1	3x40 + 3x10 mL
BT35-200	Glucose Mono	4x50 mL
BT37-250	GOT/AST 4+1	4x50 + 4x12,5 mL
BT39-250	GPT/ALT 4+1	4x50 + 4x12,5 mL
BT30-125	Iron FER 4+1	2x50 + 2x12,5 mL
BT31-125	Iron FZN 4+1	2x50 + 2x12,5 mL
BT56-60	Lactate Mono	3x20 mL
BT42-125	LDH 4+1	2x50 + 2x12,5 mL
BT43-64	Lipase 5+3	2x20 + 2x12 mL
BT47-100	Magnesium XIL Mono	5x20 mL
BT40-50	Pancreatic Amylase EPS 4+1	2x20 + 2x5 mL
BT33-100	Phosphorus Mono	2x50 mL
BT49-200	Total Proteins Mono	4x50 mL
BT50-100	Total Proteins Urine Mono	2x50 mL
BT53-200	Triglycerides Mono	4x50 mL
BT54-250	Urea UV 4+1	4x50 + 4x12,5 mL
BT02-200	Uric acid Mono	4x50 mL
BT55-50S	Zinc 4+1	2x20 + 2x5 mL
HP01-80	ACE Mono	2x40 mL
HP04-250	Albumin Mono	5x50 mL

HP28-100S	Alcohol (Ethanol) 4+1	2x40 + 2x10 mL
HP32-240	Alkaline Phosphatase DGKC 4+1	4x48+4x12 mL
HP05-100	Amylase CNPG3 Mono	2x50
HP07-80S	Bicarbonate Mono	2x40
HP08-240	Direct Bilirubin JEN 4+1	4x48 + 4x12 mL
HP09-240	Direct Bilirubin DPD 4+1	4x48 + 4x12 mL
HP10-240	Total Bilirubin JEN 4+1	4x48 + 4x12 mL
HP11-240	Total Bilirubin DPD 4+1	4x48 + 4x12 mL
HP14-250	Calcium ARS Mono	5x50 mL
HP16-120	Calcium OCP 4+1	2x48 + 2x12 mL
HP20-250	Chlorides Mono	5x50 mL
HP21-250	Cholesterol Mono	5x50 mL
HP22-120	Cholesterol HDL 3+1	2x45 + 2x15 mL
HP24-120	Cholesterol LDL 3+1	2x45 + 2x15 mL
HP25-120	Cholinesterase 5+1	2x50 + 2x10 mL
HP18-100	CK MB 4+1	2x40 + 2x10 mL
HP19-100	CK NAC 4+1	2x40 + 2x10 mL
HP52-100	Copper 4+1	2x40 + 2x10 mL
HP57-240	Creatinine JAF 4+1	4x48 + 4x12 mL
HP34-120	Gamma GT 4+1	2x48 + 2x12 mL
HP35-250	Glucose Mono	5x50 mL
HP37-240	GOT/AST 4+1	4x48 +4x12 mL
HP39-240	GPT/ALT 4+1	4x48+4x12 mL
HP30-120S	Iron FER 4+1	2x48 + 2x12 mL
HP31-120S	Iron FZN 4+1	2x48 + 2x12 mL
HP56-80	Lactate Mono	2x40 ml
HP42-240	LDH 4+1	4x48 + 4x12 mL
HP43-64	Lipase 5+3	2x20+2x12 mL
HP47-100	Magnesium XIL Mono	2x50 mL
HP40-120	Pancreatic Amylase EPS 4+1	2x48 + 2x12 mL
HP33-250	Phosphorus Mono	5x50 mL
HP49-250	Total Proteins Mono	5x50 mL
HP50-100S	Total Proteins Urine Mono	2x50 mL
HP53-250	Triglycerides Mono	5x50 mL
HP54-240	Urea UV 4+1	4x48+4x12 mL
HP02-250	Uric acid Mono	5x50 mL
HP55-100S	Zinc 4+1	2x40+2x10 mL
HG01-80	ACE Mono	2x40 mL
HG04-480	Albumin Mono	8x60 mL
HG28-100S	Alcohol (Ethanol) 4+1	2x40 + 2x10 mL
HG32-450	Alkaline Phosphatase DGKC 4+1	6x60+6x15 mL
HG05-240	Amylase CNPG3 Mono	4x60 mL
HG07-120S	Bicarbonate Mono	2X60 mL
HG08-450	Direct Bilirubin JEN 4+1	6x60 + 6x15 mL
HG09-450	Direct Bilirubin DPD 4+1	6x60+6x15 mL
HG10-450	Total Bilirubin JEN 4+1	6x60 + 6x15 mL
HG11-450	Total Bilirubin DPD 4+1	6x60+6x15 mL

HG14-480	Calcium ARS Mono	8x60 mL
HG16-450	Calcium OCP 4+1	6x60 + 6x15 mL
HG20-480	Chlorides Mono	8x60 mL
HG21-480	Cholesterol Mono	8x60 mL
HG22-120	Cholesterol HDL 3+1	2x45 + 2x15 mL
HG24-120	Cholesterol LDL 3+1	2x45 + 2x15 mL
HG25-120	Cholinesterase 5+1	2x50 + 2x10 mL
HG18-150	CK MB 4+1	2x60 + 2x15 mL
HG19-300	CK NAC 4+1	4x60 + 4x15 mL
HG52-150	Copper 4+1	2x60 + 2x15 mL
HG57-450	Creatinine JAF 4+1	6x60 + 6x15 mL
HG34-300	Gamma GT 4+1	4x60 + 4x15 mL
HG35-480	Glucose Mono	8x60 mL
HG37-450	GOT/AST 4+1	6x60 + 6x15 mL
HG39-450	GPT/ALT 4+1	6x60 + 6x15 mL
HG30-300S	Iron FER 4+1	4x60 + 4x15 mL
HG31-300S	Iron FZN 4+1	4x60 + 4x15 mL
HG56-120	Lactate Mono	2x60 mL
HG42-300	LDH 4+1	4x60 + 4x15 mL
HG43-160	Lipase 5+3	4x25 + 4x15 mL
HG47-120	Magnesium XIL Mono	2x60 mL
HG40-150	Pancreatic Amylase EPS 4+1	2x60 + 2x15 mL
HG33-480	Phosphorus Mono	8x60 mL
HG49-480	Total Proteins Mono	8x60 mL
HG50-120S	Total Proteins Urine Mono	2x60 mL
HG53-480	Triglycerides Mono	8x60 mL
HG54-450	Urea UV 4+1	6x60 + 6x15 mL
HG02-480	Uric acid Mono	8x60 mL
HG55-150S	Zinc 4+1	2x60 + 2x15 mL
OL01-80	ACE Mono	2x40 mL
OL04-120	Albumin Mono	4x30 mL
OL04-480	Albumin Mono	8x60 mL
OL28-100S	Alcohol (Ethanol) 4+1	2x40 + 2x10 mL
OL32-450	Alkaline Phosphatase DGKC 4+1	6x60+6x15 mL
OL05-60	Amylase CNPG3 Mono	4x15 mL
OL05-120	Amylase CNPG3 Mono	4x30 mL
OL07-120S	Bicarbonate Mono	2X60 mL
OL08-450	Direct Bilirubin JEN 4+1	6x60 + 6x15 mL
OL09-300	Direct Bilirubin DPD 4+1	4x60 + 4x15 mL
OL10-450	Total Bilirubin JEN 4+1	6x60 + 6x15 mL
OL11-450	Total Bilirubin DPD 4+1	6x60 + 6x15 mL
OL14-480	Calcium ARS Mono	8x60 mL
OL16-450	Calcium OCP 4+1	6x60 + 6x15 mL
OL20-120	Chlorides Mono	4x30 mL
OL21-480	Cholesterol Mono	8x60 mL
OL22-120	Cholesterol HDL 3+1	2x45 + 2x15 mL
OL24-60	Cholesterol LDL 3+1	1x45 + 1x15 mL

OL25-120	Cholinesterase 5+1	2x50 + 2x10 mL
OL18-75	CK MB 4+1	2x30 + 2x7,5 mL
OL19-150	CK NAC 4+1	4x30 + 4x7,5 mL
OL52-150	Copper 4+1	2x60 + 2x15 mL
OL57-450	Creatinine JAF 4+1	6x60 + 6x15 mL
OL34-300	Gamma GT 4+1	4x60 + 4x15 mL
OL35-480	Glucose Mono	8x60 mL
OL37-450	GOT/AST 4+1	6x60 + 6x15 mL
OL39-450	GPT/ALT 4+1	6x60 + 6x15 mL
OL30-300S	Iron FER 4+1	4x60 + 4x15 mL
OL31-300S	Iron FZN 4+1	4x60 + 4x15 mL
OL56-60	Lactate Mono	2x30 mL
OL42-150	LDH 4+1	4x30 + 4x7,5 mL
OL43-80	Lipase 5+3	2x25 + 2x15 mL
OL47-120	Magnesium XIL Mono	4x30 mL
OL40-75	Pancreatic Amylase EPS 4+1	2x30 + 2x7,5 mL
OL33-120	Phosphorus Mono	4x30 mL
OL49-240	Total Proteins Mono	4x60 mL
OL50-120S	Total Proteins Urine Mono	2x60 mL
OL53-480	Triglycerides Mono	8x60 mL
OL54-450	Urea UV 4+1	6x60 + 6x15 mL
OL02-120	Uric acid Mono	4x30 mL
OL55-150S	Zinc 4+1	2x60 + 2x15 mL

are in compliance with European Directive 98/79/CE, about the IVDD.

The products have been CE marked as other IVD Medical Device according to Annex III as they are neither in List A nor in List B of Annex II of the Directive 98/79/EC.

He moreover declares that FAR srl has a Quality System in place, which is in compliance with UNI EN ISO 9001:2015 and 13485:2016 regulation.

Pescantina (Verona - ITALY),
May 12, 2023

Dr Renzo RONCA
General Manager

