

DECLARATION OF CONFORMITY



The undersigned Erba Lachema s.r.o., having its seat in Brno, Karásek 2219/1d, Czech Republic, manufacturer of diagnostic devices, with Company Quality Management System in compliance with standards ISO 9001 and ISO 13485,

declares, that the devices listed in the annex to this declaration, comply with all the essential requirements listed in Annex I of Directive 98/79/EC and obligations specified in Annex III, art. 2 – 5 of Directive 98/79/EC for In vitro Medical-Diagnostic Devices.

Therefore Erba Lachema s.r.o. declares and assures the following:

1. the devices listed in the annex to this declaration comply with the applicable provisions of Directive 98/79/EC.
2. the devices listed in the annex to this declaration is not included in the list A and B of the Annex II of Directive 98/79/EC.
3. the manufacturer declares to have established a procedure and to maintain it in order to assure the post-marketing surveillance, according to the Directive of 98/79/EC.

Date of issue: 20.12.2017



Milena Rikanová
Representative of Quality Management

Annex to the Declaration:

Diagnostic kits		
Cat. number	Product name	Pack Name
BLT00001	ALBUMIN	ALB 250
BLT00002	ALBUMIN	ALB 500
XSYS0001	ALBUMIN	ALB 440
BLT00003	ALKALINE PHOSPHATASE	ALP AMP 150
BLT00004	ALKALINE PHOSPHATASE	ALP AMP 500
XSYS0002	ALKALINE PHOSPHATASE	ALP 110
BLT00005	ALKALINE PHOSPHATASE MEG	ALP MEG 500
BLT00006	ALPHA AMYLASE (SINGLE REAGENT)	AMY SINGLE 100
XSYS0003	ALPHA AMYLASE (SINGLE REAGENT)	AMY 110
XSYS0091	ALPHA AMYLASE (SINGLE REAGENT)	AMY 440 XL-1000
BLT00007	ALPHA AMYLASE	AMY 250
BLT00008	ALPHA AMYLASE	AMY 500
BLT00052	ALT/GPT	ALT/GPT 250
BLT00053	ALT/GPT	ALT/GPT 500
XSYS0017	ALT/GPT	ALT/GPT 330
XSYS0074	ALT/GPT	ALT/GPT 564 XL-1000
BLT00050	AST/GOT	AST/GOT 250
BLT00051	AST/GOT	AST/GOT 500
XSYS0016	AST/GOT	AST/GOT 330
XSYS0073	AST/GOT	AST/GOT 564 XL-1000
BLT00009	BILIRUBIN DIRECT	BIL D 200
XSYS0028	BILIRUBIN DIRECT	BIL D 330
BLT00010	BILIRUBIN TOTAL	BIL T 200
XSYS0023	BILIRUBIN TOTAL	BIL T 330
BLT00011	BILIRUBIN TOTAL&DIRECT	BIL T&D 200
BLT00012	BILIRUBIN TOTAL JENDRASSIK GROF	BIL T JG 350
BLT00013	BILIRUBIN TOTAL JENDRASSIK GROF	BIL T JG 350 S
BLT00014	BILIRUBIN DIRECT JENDRASSIK GROF	BIL D JG 300
BLT00078	BILIRUBIN DIRECT DCA	BIL D DCA 500
XSYS0086	BILIRUBIN DIRECT DCA	BIL D DCA 330
BLT00077	BILIRUBIN TOTAL DCA	BIL T DCA 500
XSYS0087	BILIRUBIN TOTAL DCA	BIL T DCA 330
BLT00015	CALCIUM	CA 100

BLT00016	CALCIUM	CA 250
XSYS0007	CALCIUM	CA 120
XSYS0092	CALCIUM	CA 220 XL-1000
BLT00017	CREATINE KINASE	CK 100
XSYS0022	CREATINE KINASE	CK 110
BLT00086	CREATINE KINASE	CK 250
BLT00018	CREATINE KINASE MB	CK MB 100
XSYS0029	CREATINE KINASE MB	CK MB 110
BLT00019	CREATININE	CREA 1000
BLT00020	CREATININE	CREA 200
BLT00021	CREATININE	CREA 500 S
BLT00022	CREATININE	CREA 500
XSYS0024	CREATININE	CREA 275
XSYS0076	CREATININE	CREA 564 XL-1000
BLT00065	CREATININE ENZYMATIC	CREA ENZ 204
XSYS0085	CREATININE ENZYMATIC	CREA ENZ 200
BLT00080	ERBA NORM	ERBA NORM
BLT00081	ERBA PATH	ERBA PATH
XSYS0082	ERBA XL AutoWash AC/AL	XL AUTOWASH AC/AL
BLT00023	GAMMAGLUTAMYLSTRANSFERASE	GGT 100
BLT00024	GAMMAGLUTAMYLSTRANSFERASE	GGT 250
XSYS0011	GAMMAGLUTAMYLSTRANSFERASE	GGT 110
XSYS0077	GAMMAGLUTAMYLSTRANSFERASE	GGT 330 XL-1000
BLT00025	GLUCOSE	GLU 500
BLT00026	GLUCOSE	GLU 4x250
BLT00027	GLUCOSE	GLU 1000
XSYS0012	GLUCOSE	GLU 440
XSYS0069	GLUCOSE	GLU 576 XL-1000
BLT00028	HDL DIRECT	HDL 80
BLT00029	HDL DIRECT	HDL 160
XSYS0043	HDL DIRECT	HDL C 160
XSYS0078	HDL DIRECT	HDL C 360 XL-1000
BLT00072	HDL CHOLESTEROL CALIBRATOR	HDL C CAL
BLT00030	HDL CHOLESTEROL DIRECT	HDL C DIRECT 240
XSYS0061	HDL/LDL CAL	HDL/LDL CAL
BLT00032	HDL PREC	HDL PREC 100
BLT00079	CHEM WASH	CHEM WASH

BLT00033	CHLORIDE	CL 250
XSYS0008	CHLORIDE	CL 120
BLT00034	CHOLESTEROL	CHOL 5x50
BLT00035	CHOLESTEROL	CHOL 1000
BLT00036	CHOLESTEROL	CHOL 250
XSYS0009	CHOLESTEROL	CHOL 440
XSYS0070	CHOLESTEROL	CHOL 576 XL-1000
BLT00066	CHOLINESTERASE	CHE 120
XSYS0049	IRON	FE 125
XSYS0089	IRON	FE 220 XL-1000
BLT00037	LACTATEDEHYDROGENASE-P	LDH 100
XSYS0013	LACTATEDEHYDROGENASE-P	LDH 110
BLT00038	LACTATEDEHYDROGENASE-L	LDH-L 100
BLT00039	LACTATEDEHYDROGENASE-L	LDH-L 250
BLT00041	LDL DIRECT	LDL 80
XSYS0044	LDL DIRECT	LDL C 80
BLT00073	LDL CHOLESTEROL CALIBRATOR	LDL C CAL
BLT00042	LDL CHOLESTEROL DIRECT	LDL C DIRECT 80
BLT00043	LDL CHOLESTEROL DIRECT	LDL C DIRECT 240
XSYS0081	LIPASE	LIP 110
BLT00049	MAGNESIUM	MG 250
XSYS0040	MAGNESIUM	MG 88
BLT00045	MICROPROTEIN	MP 100
XSYS0027	MICROPROTEIN	MP 120
BLT00067	PANCREATIC AMYLASE	P AMY 100
BLT00047	PHOSPHORUS	PHOS 100
BLT00048	PHOSPHORUS	PHOS 250
XSYS0015	PHOSPHORUS	PHOS 120
XSYS0093	PHOSPHORUS	PHOS 220 XL-1000
BLT00054	TOTAL PROTEIN	TP 250
BLT00055	TOTAL PROTEIN	TP 500
XSYS0018	TOTAL PROTEIN	TP 440
BLT00057	TRIGLYCERIDES	TP 100
BLT00058	TRIGLYCERIDES	TP 1000
BLT00059	TRIGLYCERIDES	TG 250
XSYS0041	TRIGLYCERIDES	TG 440
XSYS0071	TRIGLYCERIDES	TG 576 XL-1000

XSYS0050	UIBC	UIBC 125
XSYS0090	UIBC	UIBC 200 XL-1000
BLT00060	UREA	UREA 1000
BLT00061	UREA	UREA 250
XSYS0020	UREA	UREA 275
XSYS0075	UREA	UREA 564 XL-1000
BLT00062	URIC ACID (SINGLE REAGENT)	UA SINGLE 200
XSYS0042	URIC ACID (SINGLE REAGENT)	UA 440
XSYS0072	URIC ACID (SINGLE REAGENT)	UA 576 XL-1000
XSYS0021	URIC ACID	UA 275
BLT00063	URIC ACID AOD	UA 500
BLT00064	URIC ACID AOD	UA 500 S
XSYS0064	XL Calibrant A	XL CAL A
XSYS0065	XL Calibrant B	XL CAL B
XSYS0034	XL MULTICAL	XL MULTICAL
XSYS0062	XL ISE CLEANING	XL ISE CLEAN
XSYS0067	XL Urine Diluent	XL URINE DIL
XSYS0066	XL WASH	XL WASH