

## DECLARATION OF CONFORMITY



The undersigned Erba Lachema s.r.o., having its seat in Brno, Karásek 2219/1 d, 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.

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Representative of Quality Management

**Annex to the Declaration**

<b>Diagnostic kits</b>		
<b>Cat. number</b>	<b>Product name</b>	<b>Pack Name</b>
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 MG	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	BILD 330
BLT00010	BILIRUBIN TOTAL	BIL T 200
XSYS0023	BILIRUBIN TOTAL	BIL T 330
BLT00011	BILIRUBIN TOTAL&DIRECT	BILT&D 200

BLT00012	BILIRUBIN TOTAL JENDRASSIK GROF	BILT JG 350
BLT00013	BILIRUBIN TOTAL JENDRASSIK GROF	BIL T JG 350 S
BLT00014	BILIRUBIN DIRECT JENDRASSIK GROF	BIL D JG 300
BLT00078	BILIRUBIN DIRECT DC A	BIL D DCA 500
XSYS0086	BILIRUBIN DIRECT DCA	BILD 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	CKMB 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	GGT100
BLT00024	GAMMAGLUTAMYLSTRANSFERASE	GGT 250

XSYS0011	GAMMAGLUTAMYLSTRANSFERASE	GGT110
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
BLT00043	LDL CHOLESTEROL DIRECT	LDL C DIRECT 80
BLT00042	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
XSYS0063	XL ISE 4 CLEANING	XL ISE 4 CLEAN
XSYS0068	XL ISE REAGENT PACK	-
XSYS0067	XL Urine Diluent	XL URINE DIL
XSYS0066	XL WASH	XL WASH

**Imunoturbidimetry product range**

<b>Cat. number</b>	<b>Product name</b>	<b>Pack name</b>
BLT20001	ANTISTREPTOLYSIN (O)	ASO 10
BLT20002	ANTISTREPTOLYSIN (O)	ASO 5
XSYS0046	ANTISTREPTOLYSIN (O)	ASO
XSYS0051	ASO CALIBRATOR	ASO CAL SH
BLT20003	ASO CALIBRATOR	ASO CAL
BLT20004	ASO CONTROL	ASO CON
BLT20005	APOLIPOPROTEIN A1	APO A1
BLT20006	APOLIPOPROTEIN B	APO B
BLT20007	COMPLEMENT C3	C3
BLT20008	COMPLEMENT C4	C4
BLT20009	C-REACTIVE PROTEIN	CRP 10
XSYS0047	C-REACTIVE PROTEIN	CRP

BLT20010	C-REACTIVE PROTEIN	CRP 5
XSYS0094	C-REACTIVE PROTEIN	CRP 276 XL-1000
BLT20011	C-REACTIVE PROTEIN HIGH SENSITIVE	CRP-HS 10
XSYS0084	C-REACTIVE PROTEIN HIGH SENSITIVE	CRP-HS
XSYS0088	CRP-HS CALIBRATOR	CRP-HS CAL
XSYS0053	CRP CALIBRATOR	CRP CAL SH
BLT20013	CRP CONTROL	CRP CON H
BLT20014	CRP CONTROL	CRP CON L
BLT20015	FERRITIN	FERR
BLT20016	FERRITIN CALIBRATOR SET	FERR CAL SET
BLT20017	FERRITIN CONTROL HIGH	FERR CON H
XSYS0054	HbA1c	HBA1C
XSYS0057	HbA1c CALIBRATOR SET	HBA1C CAL SET
XSYS0056	HbA1c CONTROL	HBA1C CON H
XSYS0055	HbA1c CONTROL	HBA1C CON L
BLT20026	IMMUNOGLOBULIN A	IgA
BLT20027	IMMUNOGLOBULIN G	IgG
BLT20028	IMMUNOGLOBULIN M	IgM
BLT20029	LIPOPROTEIN (a)	Lp (a)
BLT20030	MICROALBUMIN	MAL 10
BLT20031	MICROALBUMIN	MAL 5
XSYS0083	MICROALBUMIN	MAL
BLT20032	MAL CALIBRATOR	MAL CAL
BLT20033	MAL CONTROL	MAL CON
BLT20034	MULTICONTROL LEVEL 1	MULTICON L1
BLT20035	MULTICONTROL LEVEL 2	MULTICON L2
XSYS0048	RHEUMATOID FACTOR	RF
BLT20038	RHEUMATOID FACTOR	RF CAL
BLT20036	RHEUMATOID FACTOR	RF 25

BLT20037	RHEUMATOID FACTOR	RF 5
XSYS0052	RF CALIBRATOR	RF CAL SH
BLT20039	RF CONTROL	RF CON
<b>Hematology product range</b>		
<b>Cat. number</b>	<b>Product name</b>	
50003762	ELite 3 (open)	
50004170	ELite 3 (closed)	
HEM00012	ELite HEM Calibrator	
50003832	ELite 3 HEM Control Low	
50003833	ELite 3 HEM Control Normal	
50003834	ELite 3 HEM Control High	
50003767	Erba Cleaner	
50003766	Erba Diff-5P	
50003774	Erba Dil-5P	
50003763	Erba Diluent-Diff	
50003773	Erba Hypoclean CC	
50003765	Erba Lyse-5P	
50004171	Erba Lyse-Diff (open)	
50003764	Erba Lyse-Diff (closed)	
50003760	ELite 5	
50004244	ELite 5 HEM Control Low	
50004245	EUte 5 HEM Control Normal	
50004246	ELite 5 HEM Control High	
50004376	Erba Hypoclean	
50004375	Erba Clenz	
INS00071	ELite 580	
HEM00019	ELite H580 Dil	
HEM00020	ELite H580 Lyse 1	
HEM00021	ELite H580 Lyse 2	



HEM00022	ELite H580 Lyse 3	
HEM00023	ELite H Clean	
HEM00024	ELite H5 CON L	
HEM00025	ELite H5 CON N	
HEM00026	ELite H5 CON H	
HEM00027	ELite H CAL	
<b>Microbiology</b>		
<b>Cat. number</b>	<b>Product name</b>	
MLT00001	ANAERObtest 23	
MLT00002	CANDIDAbtest 21	
MLT00003	CANDIDA-Screen	
MLT00004	EN-COCCUStest	
MLT00005	ENTERObtest 16	
MLT00007	ENTERO-Rapid 24	
MLT00008	ENTERObtest 24 N	
MLT00009	ENTERO-Screen	
MLT00010	NEFERMtest 24	
MLT00011	NEISSERIAtest	
MLT00012	STAPHYtest 16	
MLT00013	STAPHYtest 24	
MLT00014	STREPTObtest 16	
MLT00015	STREPTObtest 24	
MLT00016	Reagent for ACETOIN test	
MLT00017	Reagent for PHENYLALANINE test	
MLT00018	Reagent for PHOSPHATASE test	
MLT00019	Reagent for HIPPURATE test	
MLT00020	Reagent for INDOL test	
MLT00021	Reagent for NITRATE test	
MLT00022	Reagent for OXIDASE test	

MLT00023	Reagent for PYR test	
MLT00024	Suspension medium for ANAEROTest 23	
MLT00025	Suspension medium for NEISSERIAtest	
MLT00026	Suspension medium for STREPTOTest 16	
MLT00027	Suspension medium for STREPTOTest 24	
MLT00028	INDOLtest	
MLT00029	mCOLItest	
MLT00030	m OX I test	
MLT00031	NITROCEFAN	
MLT00032	OFtest	
MLT00033	URE-HPtest	
MLT00034	β-LACTAMtest	
MLT00035	COLItest	
MLT00036	HIPPURATEtest	
MLT00037	INDOXYLtest	
MLT00038	ONPtest	
MLT00039	OX I test	
MLT00040	PYRAtest	
MLT00041	VPtest	
MLT00042	PARAFFIN OIL STERILIZED	
MLT00043	MIC G+	
MLT00044	MIC G-I	
MLT00045	MIC G-II	
MLT00046	MIC NEFERM	
MLT00047	MIC STAPHY	
MLT00048	MIC URINE	
MLT00049	MIC Amikacin	
MLT00050	MIC Ampicillin	
MLT00051	MIC Ampicillin/Sulbactam	

MLT00052	MIC Cefepime	
MLT00053	MIC Ceftazidime	
MLT00054	MIC Cefuroxime	
MLT00055	MIC Ciprofloxacin	
MLT00056	MIC Clindamycin	
MLT00057	MIC Colistin	
MLT00058	MIC Ertapenem	
MLT00059	MIC Gentamicin	
MLT00060	MIC Imipenem	
MLT00061	MIC Linezolid	
MLT00062	MIC Meropenem	
MLT00063	MIC Nitrofurantoin	
MLT00064	MIC Penicillin	
MLT00065	MIC Piperacillin/Tazobactam	
MLT00066	MIC Teicoplanin	
MLT00067	MIC Trimethoprim/Sulfamethoxazole	
MLT00068	MIC Vancomycin	
MLT00069	MIC Tigecycline	
MLT00070	Suspension medium MIC	
MLT00071	Suspension medium MIC G+	
MLT00072	Suspension medium MIC Mini	
MLT00073	Suspension medium MIC G+ Mini	
MLT00074	Suspension medium MIC G+ 200	
MLT00075	Suspension medium MIC G+ 200	
MLT00076	SENSILAtest G+	
MLT00077	SENSILAtest G-I	
MLT00078	SENSILAtest G-II	
MLT00079	SENSILAtest NEFERM	
MLT00080	SENSILAtest STAPHY	

MLT00081	SENSILAtest URINE	
MLT00082	Suspension medium for SENSILATEST	
MLT00083	BACITRACIN 10 UI	
MLT00084	BACITRACIN S	
MLT00085	NOVOBIOCIN	
MLT00086	OPTOCHIN	
MLT00087	V+KDISK	
MLT00088	V-FAKTOR	
MLT00089	X-FAKTOR	
MLT00090	X+V-FAKTOR	
INS00062	DENSILAMETER II	
INS00069	ErbaFill	

**Urine Analysis**

<b>Cat. number</b>	<b>Product name</b>	
URPH0001	ALBUPHAN	
URPH0002	GLUKOPHAN	
URPH0003	HEMOPHAN	
URPH0004	KETOPHAN	
URPH0005	DIAPHAN	
URPH0006	IKTOPHAN	
URPH0007	TRIPHAN	
URPH0008	TRIPHAN /100	
URPH0009	TETRAPHAN DiA	
URPH0010	PENTAPHAN	
URPH0011	HEXAPHAN	
URPH0012	HEXAPHAN/100	
URPH0013	HEPTAPHAN	
URPH0014	HEPTAPHAN /100	
URPH0015	NONAPHAN SG	

URPH0016	NEFROPHAN LEUCO	
URPH0017	DEKAPHAN LEUCO	
URPH0018	DEKAPHAN LEUCO /100	
URPH0019	UNDEKAPHAN	
URPH0020	MICROALBUPHAN	
URPH0021	Uro-dip 10 e	
URPH0024	DIAPHAN LAURA	
URPH0025	TETRAPHAN SG LAURA	
URPH0026	PENTAPHAN LAURA	
URPH0027	HEPTAPHAN LAURA	
URPH0028	DEKAPHAN LAURA	
URPH0029	MICROALBUPHAN LAURA	
URPH0030	DekaPHAN Auto	
URPH0031	UndekaPHAN Auto	
URPH0032	UNDEKAPHAN LAURA	
URPH1001	Control strips for LAURA M	
URPH1002	Control strips for LAURA	
URPH1003	Control strips for LAURA SMART	
50001727	LAURA	
50003508/ INS00064	LAURA SMART	
INS00065	LAURA XL	
INS00073	LAURA M	
REG00053	URINORM	
REG00054	Opti-sol XL 750	
REG00055	Opti-sol XL 1500	
<b>ERBA LYTE</b>		
<b>Cat. number</b>	<b>Product name</b>	
INS00022	ERBA LYTE ANALYSER	
1NS00023	ERBA LYTE PLUS ANALYSER	

INS00024	ERBA LYTE Li ANALYSER	
INS00025	ERBA LYTE Li PLUS ANALYSER	
INS00026	ERBA LYTE Ca ANALYSER	
INS00027	ERBA LYTE PRO ANALYSER	
INS00028	ERBA LYTE PRO PLUS ANALYSER	
INS00029	ERBA LYTE Ca PLUS ANALYSER	
REG00001	ERBA LYTE QC SOLUTION	
REG00002	ERBA LYTE CLEANING SOLUTION	
REG00003	ERBA LYTE C02 STANDARD	
REG00004	ERBA LYTE K ELECTRODE FILL SOLUTION	
REG00005	ERBA LYTE Na, Cl, pH ELECTRODE FILL SOLUTION	
REG00006	ERBA LYTE Ca ELECTRODE FILL SOLUTION	
REG00007	ERBA LYTE Li ELECTRODE FILL SOLUTION	
REG00008	ERBA LYTE REFERENCE ELECTRODE FILL SOLUTION	
REG00009	ERBA LYTE URINE DILUENT	
REG00010	ERBA LYTE Na CONDITIONER (NaF)	
REG00011	ERBA LYTE PLUS REAGENT PACK	
REG00012	ERBA LYTE Ca REAGENT PACK	
REG00013	ERBA LYTE PRO REAGENT PACK	
REG00014	ERBA LYTE PRO PLUS REAGENT PACK	
REG00015	ERBA LYTE Li REAGENT PACK	
REG00016	ERBA LYTE Li STANDARD	
REG00017	ERBA LYTE Li QC SOLUTION (high)	
REG00018	ERBA LYTE Li QC SOLUTION (low)	
REG00019	ERBA LYTE Ca QC SOLUTION	
<b>Instruments</b>		
<b>Cat. number</b>	<b>Product name</b>	
INS00031	ERBA LISASCAN II	
INS00032	ERBA LISAWASH	

<b>Coagulation product range</b>		
<b>Cat. number</b>	<b>Product name</b>	
EHL00003	Erba Actime	
EHL00004	Erba Actime	
EHL00020	Erba Calcium Chloride	
EHL00014	Erba Control N	
EHL00016	Erba Control N Plus	
EHL00015	Erba Control P	
EHL00017	Erba Control P Plus	
EHL00018	Erba DDimer Calibrator	
EHL00044	Erba DDimer Calibrator	
EHL00045	Erba Protime R	
EHL00019	Erba DDimer Control N+P	
EHL00040	Erba DDimer B	
EHL00041	Erba DDimer B	
EHL00011	Erba DDimer R	
EHL00028	Erba DDimer R	
EHL00008	Erba Chrom Antithrombin III	
EHL00009	Erba Chrom Protein C	
EHL00039	Erba LA Control High	
EHL00037	Erba LA1 Screen	
EHL00038	Erba LA2 Confirm	
EHL00021	Erba Owrens Veronal Buffer	
EHL00010	Erba Protein S Clotting	
EHL00001	Erba Protime	
EHL00002	Erba Protime	
EHL00027	Erba Protime	
EHL00023	Erba Protime LS 4	
EHL00024	Erba Protime LS 10	

EHL00046	Erba Protime LS 50	
EHL00047	Erba Protime LS 100	
EHL00013	Erba PT-INR Multical	
EHL00012	Erba Standard Plasma	
EHL00005	Erba Thrombin Reagent	
EHL00006	Erba Thrombin Reagent	
EHL00025	Erba Thrombin Reagent	
EHL00007	Erba Thrombin Time	
EHL00026	Erba Thrombin Time	
EHL00029	Erba Factor II Deficient Plasma	
EHL00030	Erba Factor V Deficient Plasma	
EHL00031	Erba Factor VII Deficient Plasma	
EHL00032	Erba Factor X Deficient Plasma	
EHL00033	Erba Factor VIII Deficient Plasma	
EHL00035	Erba Factor XI Deficient Plasma	
EHL00036	Erba Factor XII Deficient Plasma	
EHL00034	Erba Factor IX Deficient Plasma	
EHL00035	Erba Factor XI Deficient Plasma	
EHL00036	Erba Factor XII Deficient Plasma	
EHL00042	Erba Clean I	
EHL00043	Erba Clean II	
EHL00022	Erba Clean III	
INS00059	ECL 105	
INS00060	ECL 412	
INS00070	ECL 760	
<b>Hb-Vario</b>		
<b>Cat. number</b>	<b>Product name</b>	
INS00055	Hb-Vario Analyser	
REG00038	Hb-Vario Kit	



REG00039	Hb-Vario HbA1c Calibrator Set CM	
REG00040	Hb-Vario HbA1c Calibrator Set	
REG00041	Hb-Vario HbA1c Control Set	
REG00042	Hb-Vario Hemolyser Reagent	
REG00043	Hb-Vario Cleaner Solutions	
REG00044	Hb-Vario Complete Kit	