

EC DECLARATION OF CONFORMITY

We, BEN S.r.l. Biochemical Enterprise – a socio unico (BEN S.r.l),
as a manufacturer registered at and located in Via P. Toselli, 4 - 20127 Milan - ITALY and having VAT
N° IT 07351500157, hereby declare that:
the "In Vitro Diagnostic" Reagents manufactured by BEN S.r.l. and placed on the worldwide market:

under its own name and label, BEN S.r.l., having affixed the  mark

comply with all Essential Requirements of the IVD European Directive 98/79/EC of October 27th, 1998.

The Reagents fulfill all the provisions mentioned in the IVD European Directive 98/79/EC, that may be
applied to them. (Annex III). All devices are classified as: "other".

This Declaration of Conformity includes all the Reagents mentioned in the attached list (5 pages).

Declaration issued and signed in Milan on 16 December 2019.

Dr. Spartaco Berti 
BEN S.r.l. Biochemical Enterprise – a socio unico

DICHIARAZIONE CE DI CONFORMITÀ

La BEN S.r.l. Biochemical Enterprise – a socio unico (BEN S.r.l.), nella sua qualità di Fabbrikante registrato e residente in Via P. Toselli, 4 - 20127 Milano – ITALIA, avente P.IVA N° 07351500157,

qui dichiara che i Reagenti "Diagnostici In Vitro (IVD)" da Lei prodotti e posti sul mercato mondiale:

sotto il proprio nome ed etichetta, BEN S.r.l., riportanti il marchio 

sono in accordo con tutti i Requisiti Essenziali della Direttiva Europea (IVD) 98/79/CE dell'Ottobre 27, 1998 e con il Decreto Legislativo Italiano N° 332 del 08 Settembre 2000, riferiti ai dispositivi medici "diagnostici in vitro".

Questi Reagenti soddisfano tutte le disposizioni menzionate nella Direttiva Europea (IVD) 98/79/CE che possono essere applicate loro e gli obblighi imposti dal Decreto Legislativo Italiano N°332 (Allegato III). Tutti i dispositivi sono classificati come "altri".

Questa Dichiarazione di Conformità include tutti i Reagenti menzionati nell'Elenco allegato (5 pagine).

Questa Dichiarazione è stata redatta e firmata in Milano il 16 Dicembre 2019.

Dr.Spartaco Berti


BEN S.r.l. Biochemical Enterprise – a socio unico

CODICE	DESCRIZIONE	Taglio		
A2M3226	ALPHA-2-MACROGLOBULIN	2	x	20 mL
AA051	ALPHA AMYLASE liquid (PNPG7)	4	x	50 mL
AA052	ALPHA AMYLASE PANCREATIC liquid (PNPG7)	4	x	24 mL
AC8829	ACETIC ACID liquid	10	x	10 mL
ACAL8866	ACE CALIBRATOR Iyo	6	x	1 mL
ACE8864	ACE monoliquid	4	x	20 mL
ACE8865	ACE (Angiotensin Converting Enzyme)	10	x	10 mL
ADA016	ADA (Adenosine Deaminase)	5	x	20 mL
ADA018	ADA (Adenosine Deaminase)	10	x	6 mL
ADACAL	ADA CALIBRATOR Iyo	4	x	1 mL
ADACO1	ADA CONTROL Iyo	3	x	1 mL
ADACO2	ADA CONTROL for CSF	4	x	1 mL
ADACSF	ADA CALIBRATOR for CSF Iyo	3	x	1 mL
AEL8868	ACE ELEVATED CONTROL Iyo	6	x	1 mL
AL021	ALAT (GPT) liquid	4	x	50 mL
ALBG045	ALBUMIN BCG (green)	4	x	80 mL
ALD100	ALDOLASE	1	x	100 mL
ALD101	ALDOALSE (S)	1	x	100 mL
ALDOCAL	ALDOLASE CALIBRATOR Iyo	3	x	1 mL
AM8870	Ammonia	20	x	3 mL
AN3282	ANTITHROMBIN III	2	x	20 mL
ANOR8867	ACE NORMAL CONTROL Iyo	6	x	1 mL
AP010	ACID PHOSPHATASE	10	x	10 mL
AP013	ACID PHOSPHATASE	20	x	3 mL
AP041	ALKALINE PHOSPHATASE (DEA) liquid	4	x	50 mL
AP042	ALBUMIN BCP (purple)	12	x	50 mL
ARC6227	ARC(ASO, RF, CRP) CALIBRATOR elevated value	1	x	3 mL
ARC6230	ARC (ASO, RF, CRP) CALIBRATOR	5	x	1 mL
ARCCO6232	ARC (ASO, RF, CRP) CONTROL normal/elevated	2x2mL	+	2x2 mL
AS071	ASAT (GOT) liquid	4	x	50 mL
ASO6215	ANTI-STREPTOLYSIN O (ASO)	4x18 mL	+	1x8 mL
ASO6217	ANTI-STREPTOLYSIN O (ASO)	1x18 mL	+	1x2,2 mL
AT3236	ALPHA-1-ANTITRYPSIN	2	x	20 mL
AU403	URIC ACID monoliquid	4	x	80 mL
B1129	G6PDH-RED CELL LYSING REAGENT (only for automation)	4	x	25 mL
B2MI6207	BETA-2-MICROGLOBULIN	1x18 mL	+	1x2,6 mL
B2ST6206	BETA-2-MICROGLOBULIN CALIBRATOR	5	x	0,5 mL
BDC127	BILIRUBIN DIRECT Jendrassik	6	x	25 mL
BIL8903	BILE ACIDS (B) liquid	54 mL		
BILCO8901	BILE ACIDS LOW and ELEVATED CONTROLS	3x5mL	+	3x5 mL
BJ3270	BENCE JONES PROTEINS	1	x	20 mL
BK151	BUN-UV (UREA) liquid	4	x	50 mL
BTC116	BILIRUBIN TOTAL Jendrassik	6	x	25 mL
C20T5	CHOLESTEROL TOTAL liquid - monocomponent	4	x	80 mL

C24F6	CHOLESTEROL FREE	6	x	20 mL
C3F3206	C3 FACTOR	2	x	20 mL
C4F3212	C4 FACTOR	2	x	20 mL
C700	aPTT liquid	4	x	4 mL
C701	aPTT liquid	4	x	8 mL
C702	aPTT liquid (S)	4	x	4 mL
C705	COAGULATION CALIBRATOR	8	x	1 mL
C706	COAGULATION NORMAL CONTROL	8	x	1 mL
C707	COAG. ABNORMAL CONTROL LEV 1	8	x	1 mL
C708	COAG. ABNORMAL CONTROL LEV 2	8	x	1 mL
C712	PT (Prothrombin Time) Liquid-F	8	x	5 mL
C713	PT (Prothrombin Time) Liquid	8	x	5 mL
C714	PT (Prothrombin Time)	4	x	4 mL
C715	PT (Prothrombin Time)	4	x	8 mL
C720	Fibrinogen Clauss	6	x	3 mL
C732	Coag Diluent	2	x	80 mL
C734	Coag Cleaning Solution	2	x	250 mL
C736	Coag Kaolin	2	x	20 mL
C738	Antithrombin III	1x6 mL	+	2x3 mL
CA165	CALCIUM ARSENAZO III	4	x	75 mL
CALFAS3	CALIBRATOR CLINICAL CHEMISTRY Iyo+diluent	5	x	3 mL
CALFRU	FRUCTOSAMINE CALIBRATOR liquid	2	x	2 mL
CALFRU2	FRUCTOSAMINE CALIBRATOR Iyo	4	x	1 mL
CALPRO1	PLASMAPROTEINS CALIBRATOR 5 concentrations	5	x	1 mL
CALPRO45	PLASMAPROTEINS CALIBRATOR elevated level	1	x	5 mL
CALPRO6	KAPPA LAMBDA URINE CALIBRATOR	5	x	1 mL
CALPRO8	IgG LIQUOR/URINE CALIBRATOR	5	x	1 mL
CE3292	CERULOPLASMIN	2	x	20 mL
CI8820	CITRIC ACID	5	x	20 mL
CI8822	CITRIC ACID	6	x	20 mL
CK271	CPK-NAC TOTAL liquid	4	x	50 mL
CL170	CHLORIDE	5	x	80 mL
CMB1	CPK-MB CALIBRATOR Iyo	3	x	1 mL
CMB2	CPK-MB ELEVATED CONTROL Iyo	4	x	1 mL
CMB274	CPK-NAC MB liquid	4	x	50 mL
CMB3	CPK-MB NORMAL CONTROL Iyo	4	x	1 mL
CNU	NORMAL CONTROL SERUM Iyo	5	x	5 mL
COP352	COPPER (DiBr-PAESA) liquid	2	X	50 mL
COPCO67	COPPER CONTROLS normal/elevated	1x5 mL	+	1x 5 mL
CPU	PATHOLOGICAL CONTROL SERUM Iyo	5	x	5 mL
CR280	CREATININE CHEMICAL (Jaffè)	6	x	50 mL
CRP6235	C REACTIVE PROTEIN (CRP)	4x18 mL	+	1x8 mL
CRP6237	C REACTIVE PROTEIN (CRP)	1x18 mL	+	1x2,2 mL
CT0111	CI+OX CALIBRATOR liquid	2	x	5 mL
DD6218	D-DIMER	2x18	x	2x6 mL

DDCAL	D-DIMER CALIBRATOR	5	x	1 mL
DDCON	D-DIMER CONTROL low/elevated	2x1	+	2x1 mL
DEP1	SOLUZIONE DEPROTEINIZZANTE	1	x	100 mL
DIB286	DIBUCAINE liquid (only for PCB261)	2	x	50 mL
ET8852	ETHANOL	20	x	3 mL
ETCH258	ETHANOL HIGH CONTROL liquid	6	x	2 mL
ETCL133	ETHANOL LOW CONTROL liquid	6	x	2 mL
FE340	IRON FERENE	5	x	80 mL
FE345	IRON FERROZINE liquid	4	x	100 mL
FE6200	FERRITIN	4x13 mL	+	1x17 mL
FE6202	FERRITIN	1x13 mL	+	1x4,6 mL
FECO6204	FERRITIN CONTROL normal/elevated	2x2mL	+	2x2 mL
FEHS6203	FERRITIN HIGH SENSITIVITY CALIBRATOR	5	x	1 mL
FEST6201	FERRITIN CALIBRATOR	5	x	1 mL
FIB3340	FIBRINOGEN	2	x	20 mL
FR289	FRUCTOSAMINE	10	x	10 mL
FRUNOR	FRUCTOSAMINE NORMAL CONTROL liquid	2	x	2 mL
FRUPAT	FRUCTOSAMINE PATHOLOGICAL CONTROL liquid	2	x	2 mL
G6CAL3	G6PDH CALIBRATORS	2	x	0,5 mL
G6CON	G6PDH CONTROLS SET	3	x	0,5 mL
G6P8905	G6PDH - GLUCOSE 6 PHOSPHATE DEHYDROGENASE	20	x	3 mL
G6P8906	G6PDH - GLUCOSE 6 PHOSPHATE DEHYDROGENASE	4	x	15 mL
G6P8910	G6PDH - GLUCOSE 6 PHOSPHATE DEHYDROGENASE SET	20	x	3 mL
GF8815	GLUCOSE-FRUCTOSE	5	x	20 mL
GL303	GLUCOSE TRINDER monoliquid	4	x	80 mL
GL316	GLUCOSE-UV (HK) liquid	4	x	50 mL
GT291	GAMMA GT liquid	4	x	50 mL
HB8855	β - HYDROXYBUTYRRIC ACID (β -HBA)	10	x	10 mL
HBCH3511	β -HBA HIGH CONTROL Iyo	6	x	1 mL
HBCL2511	β -HBA LOW CONTROL Iyo	6	x	1 mL
HBST8856	β -HBA STANDARD 3 different levels liquid	3	x	2x5 mL
HD320	CHOLESTEROL HDL direct liquid	2	x	40 mL
HD321	CHOLESTEROL HDL direct liquid	1	x	40 mL
HDLD627	CHOLESTEROL HDL/LDL CALIBRATOR Iyo	3	x	1 mL
HDLD628	CHOLESTEROL HDL/LDL CONTROL Iyo	4	x	1 mL
HP3222	HAPTOGLOBIN	2	x	20 mL
IG3201	IMMUNOGLOBULIN G (IgG)	2	x	20 mL
IG3202	IMMUNOGLOBULIN A (IgA)	2	x	20 mL
IG3203	IMMUNOGLOBULIN M (IgM)	2	x	20 mL
IGE6255	IMMUNOGLOBULIN E (IgE) Total	2x15 mL	+	2x4 mL
IGE6257	IMMUNOGLOBULIN E (IgE) Total	1x15 mL	+	1x4 mL
IGECO6259	IMMUNOGLOBULIN E (IgE) CONTROL normal/elevated	2x2mL	+	2x2 mL
IGEST6256	IMMUNOGLOBULIN E (IgE) CALIBRATOR	5	x	1 mL
INRCAL	INR Calibrators Set	6	x	1 mL
INRCAL2	INR Calibrators Set	6	x	1 mL

K390	POTASSIUM ENZYMATIC	4	x	20 mL
KA3300	KAPPA LIGHT CHAINS (FREE+BOUND)	2	x	20 mL
LA3310	LAMBDA LIGHT CHAINS (FREE+BOUND)	2	x	20 mL
LA8810	L-LACTIC ACID	5	x	20 mL
LAT8840	L-LACTATE TRINDER liquid	1	x	50 mL
LD351	LDH PYRUVATE liquid	4	x	50 mL
LDL348	CHOLESTEROL LDL direct	1	x	40 mL
LIP3542	LIPASE COLORIMETRIC liquid	2	x	18 mL
LPA6210	LIPOPROTEIN (a) - Lp(a)	4x13 mL	+	1x12 mL
LPA6212	LIPOPROTEIN (a) - Lp(a)	1x13 mL	+	1x3,2 mL
LPAC06213	LIPOPROTEIN (a)- Lp(a) CONTROL normal/elevated	2x2mL	+	2x2 mL
LPST3261	LIPOPROTEIN (a)- Lp(a) CALIBRATOR	5	x	1 mL
MG3581	MAGNESIUM CALMAGITE	2	x	100 mL
MI6260	MICROALBUMIN	1x18 mL	+	1x3,5 mL +1x1mL
NA389	SODIUM ENZYMATIC	4	x	20 mL
OCH6502	OXALATE HIGH CONTROL Iyo	6	x	2 mL
OCL6627	OXALATE LOW CONTROL Iyo	6	x	2 mL
OR3232	ALPHA-1-ACID GLYCOPROTEIN OROSOMUCOID	2	x	20 mL
OX8850	OXALATE	1	x	20 mL
OX8851	OXALATE (without tubes)	6	x	20 mL
OX8862	OXALATE - D	1	x	20 mL
OX8864	OXALATE - D (without tubes)	6	x	20 mL
OX8869	OXALATE-D (with tubes)	6	x	20 mL
OXA75	OXALATE URINE PURIFIER	75 tubes		
OXST8853	OXALATE STANDARD SET liquid	3	x	50 mL
PA3330	PREALBUMIN	2	x	20 mL
PCB260	CHOLINESTERASE BTC/DTNB	10	x	20 mL
PCB261	CHOLINESTERASE liquid	4	x	60 mL
PH331	INORGANIC PHOSPHORUS	4	x	80 mL
PK8831	PYRUVATE KINASE	20	x	3 mL
PKC032	PYRUVATE KINASE (PK) CONTROL	4	x	1 mL
PL360	PHOSPHOLIPIDS TRINDER	10	x	20 mL
PLACAL	PLASMA CALIBRATOR Iyo	3	x	0,5 mL
PLACO	PLASMA CONTROLS NORMAL and PATHOLOGICAL Iyo	2x1,5 mL	+	2x0,7 mL
PROEL	PLASMAPROTEINS ELEVATED CONTROL liquid	2	x	3 mL
PROLI7	KAPPA LAMBDA URINE CONTROL	1	x	3 mL
PROLI9	IgG LIQUOR/URINE CONTROL	1	x	3 mL
PRONOR	PLASMAPROTEINS NORMAL CONTROL liquid	2	x	3 mL
PT371	TOTAL PROTEINS	4	x	80 mL
PT375	TOTAL PROTEINS HIGH SENSITIVITY	3	x	70 mL
PY8825	PYRUVATE	10	x	10 mL
PY8826	PYRUVATE (for Automation)	5	x	20 mL
RF6225	RHEUMATOID FACTOR (RF)	4x18 mL	+	1x8 mL
RF6227	RHEUMATOID FACTOR (RF)	1x18 mL	+	1x2,2 mL
SCE3005	SUBSTRATE ELEVATED CONTROL Iyo	6	x	2 mL

SCL3006	SUBSTRATE LOW CONTROL Iyo	6	x	2 mL
TG381	TRIGLYCERIDES liquid TOOS	4	x	50 mL
TG383	TRIGLYCERIDES monoliquid p-Cl-phenol	4	x	80 mL
TG8842	GLYCEROL monoliquid	6	x	20 mL
THEMO395	TOTAL HEMOGLOBIN	4	x	40 mL
TIP401	TIP CLEANER	1	x	250 mL
TR3218	TRANSFERRIN	2	x	20 mL
URISTONE2	URINARY STONES	30 test		
URISTONE3	KIDNEY STONES	50 tests		
WSA	WASHING SOLUTION A	4	x	50 mL
WSB	WASHING SOLUTION B	4	x	50 mL
ZIN365	ZINC liquid	2	x	20 mL
ZINCO69	ZINC LOW and ELEVATED CONTROLS	1x5 mL	+	1x 5 mL