

## 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 27<sup>th</sup>, 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

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



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

<b>K390</b>	POTASSIUM ENZYMATIC	4	x	20 mL
<b>KA3300</b>	KAPPA LIGHT CHAINS (FREE+BOUND)	2	x	20 mL
<b>LA3310</b>	LAMBDA LIGHT CHAINS (FREE+BOUND)	2	x	20 mL
<b>LA8810</b>	L-LACTIC ACID	5	x	20 mL
<b>LAT8840</b>	L-LACTATE TRINDER liquid	1	x	50 mL
<b>LD351</b>	LDH PYRUVATE liquid	4	x	50 mL
<b>LDL348</b>	CHOLESTEROL LDL direct	1	x	40 mL
<b>LIP3542</b>	LIPASE COLORIMETRIC liquid	2	x	18 mL
<b>LPA6210</b>	LIPOPROTEIN (a) - Lp(a)	4x13 mL	+	1x12 mL
<b>LPA6212</b>	LIPOPROTEIN (a) - Lp(a)	1x13 mL	+	1x3,2 mL
<b>LPAC06213</b>	LIPOPROTEIN (a)- Lp(a) CONTROL normal/elevated	2x2mL	+	2x2 mL
<b>LPST3261</b>	LIPOPROTEIN (a)- Lp(a) CALIBRATOR	5	x	1 mL
<b>MG3581</b>	MAGNESIUM CALMAGITE	2	x	100 mL
<b>MI6260</b>	MICROALBUMIN	1x18 mL	+	1x3,5 mL +1x1mL
<b>NA389</b>	SODIUM ENZYMATIC	4	x	20 mL
<b>OCH6502</b>	OXALATE HIGH CONTROL Iyo	6	x	2 mL
<b>OCL6627</b>	OXALATE LOW CONTROL Iyo	6	x	2 mL
<b>OR3232</b>	ALPHA-1-ACID GLYCOPROTEIN OROSOMUCOID	2	x	20 mL
<b>OX8850</b>	OXALATE	1	x	20 mL
<b>OX8851</b>	OXALATE (without tubes)	6	x	20 mL
<b>OX8862</b>	OXALATE - D	1	x	20 mL
<b>OX8864</b>	OXALATE - D (without tubes)	6	x	20 mL
<b>OX8869</b>	OXALATE-D (with tubes)	6	x	20 mL
<b>OXA75</b>	OXALATE URINE PURIFIER	75 tubes		
<b>OXST8853</b>	OXALATE STANDARD SET liquid	3	x	50 mL
<b>PA3330</b>	PREALBUMIN	2	x	20 mL
<b>PCB260</b>	CHOLINESTERASE BTC/DTNB	10	x	20 mL
<b>PCB261</b>	CHOLINESTERASE liquid	4	x	60 mL
<b>PH331</b>	INORGANIC PHOSPHORUS	4	x	80 mL
<b>PK8831</b>	PYRUVATE KINASE	20	x	3 mL
<b>PKCO32</b>	PYRUVATE KINASE (PK) CONTROL	4	x	1 mL
<b>PL360</b>	PHOSPHOLIPIDS TRINDER	10	x	20 mL
<b>PLACAL</b>	PLASMA CALIBRATOR Iyo	3	x	0,5 mL
<b>PLACO</b>	PLASMA CONTROLS NORMAL and PATHOLOGICAL Iyo	2x1,5 mL	+	2x0,7 mL
<b>PROEL</b>	PLASMAPROTEINS ELEVATED CONTROL liquid	2	x	3 mL
<b>PROLI7</b>	KAPPA LAMBDA URINE CONTROL	1	x	3 mL
<b>PROLI9</b>	IgG LIQUOR/URINE CONTROL	1	x	3 mL
<b>PRONOR</b>	PLASMAPROTEINS NORMAL CONTROL liquid	2	x	3 mL
<b>PT371</b>	TOTAL PROTEINS	4	x	80 mL
<b>PT375</b>	TOTAL PROTEINS HIGH SENSITIVITY	3	x	70 mL
<b>PY8825</b>	PYRUVATE	10	x	10 mL
<b>PY8826</b>	PYRUVATE (for Automation)	5	x	20 mL
<b>RF6225</b>	RHEUMATOID FACTOR (RF)	4x18 mL	+	1x8 mL
<b>RF6227</b>	RHEUMATOID FACTOR (RF)	1x18 mL	+	1x2,2 mL
<b>SCE3005</b>	SUBSTRATE ELEVATED CONTROL Iyo	6	x	2 mL

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