

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
No 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 fabbricante 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	20 mL
AA051	ALPHA AMYLASE Iliquid (PNPG)	50 mL
AA052	ALPHA AMYLASE PANCREATIC Iliquid (PNPG)	24 mL
AC8829	ACETIC ACID Iliquid	10 mL
ACAL8866	ACE CALIBRATOR Iyo	1 mL
ACE8864	ACE monoliquid	20 mL
ACE8865	ACE (Angiotensin Converting Enzyme)	10 mL
ADA016	ADA (Adenosine Deaminase)	20 mL
ADA018	ADA (Adenosine Deaminase)	6 mL
ADACAL	ADA CALIBRATOR Iyo	1 mL
ADAC01	ADA CONTROL Iyo	1 mL
ADAC02	ADA CONTROL for CSF	1 mL
ADACSF	ADA CALIBRATOR for CSF Iyo	1 mL
AEL8868	ACE ELEVATED CONTROL Iyo	1 mL
AL021	ALAT (GPT) Iliquid	80 mL
ALBG045	ALBUMIN BCG (green)	4
ALD100	ALDOALASE	100 mL
ALD101	ALDOALASE (S)	100 mL
ALDOCAL	ALDOALASE CALIBRATOR Iyo	1 mL
AM8870	Ammonia	3 mL
AN3282	ANTITHROMBIN III	20 mL
ANOR8867	ACE NORMAL CONTROL Iyo	1 mL
AP010	ACID PHOSPHATASE	10 mL
AP013	ACID PHOSPHATASE	10 mL
AP041	ALKALINE PHOSPHATASE (DEA) Iliquid	20 mL
AP042	ALBUMIN BCP (purple)	4
ARC6227	ARC(ASO, RF, CRP) CALIBRATOR elevated value	12
ARC6230	ARC (ASO, RF, CRP) CALIBRATOR	1
ARCC06232	ARC (ASO, RF, CRP) CONTROL normal/elevated	5
AS071	ASAT (GOT) Iliquid	2x2 mL
AS06215	ANTI-STREPTOLYSIN O (ASO)	4
AS06217	ANTI-STREPTOLYSIN O (ASO)	4x18 mL
AT3236	ALPHA-1-ANTITRYPSIN	1x18 mL
AU403	URIC ACID monoliquid	2
B1129	G6PDH-RED CELL LYSING REAGENT (only for automation)	4
B2MI6207	BETA-2-MICROGLOBULIN	4
B2ST6206	BETA-2-MICROGLOBULIN CALIBRATOR	1x18 mL
BDC127	BILIRUBIN DIRECT Jendrassik	5
BIL8903	BILE ACIDS (B) Iliquid	6
BILCO8901	BILE ACIDS LOW and ELEVATED CONTROLS	54 mL
BJ3270	BENCE JONES PROTEINS	3x5 mL
BK151	BUN-UV (UREA) Iliquid	1
BTCL16	BILIRUBIN TOTAL Jendrassik	4
C2015	CHOLESTEROL TOTAL Iliquid - monocomponent	4

C24F6	CHOLESTEROL FREE	6	x	20 mL
C3F3206	C3 FACTOR	2	x	20 mL
CAF3212	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	2	x	20 mL
CA165	CALCIUM ARSENATO 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
C18820	CITRIC ACID	5	x	20 mL
C18822	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 (Jaffe)	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



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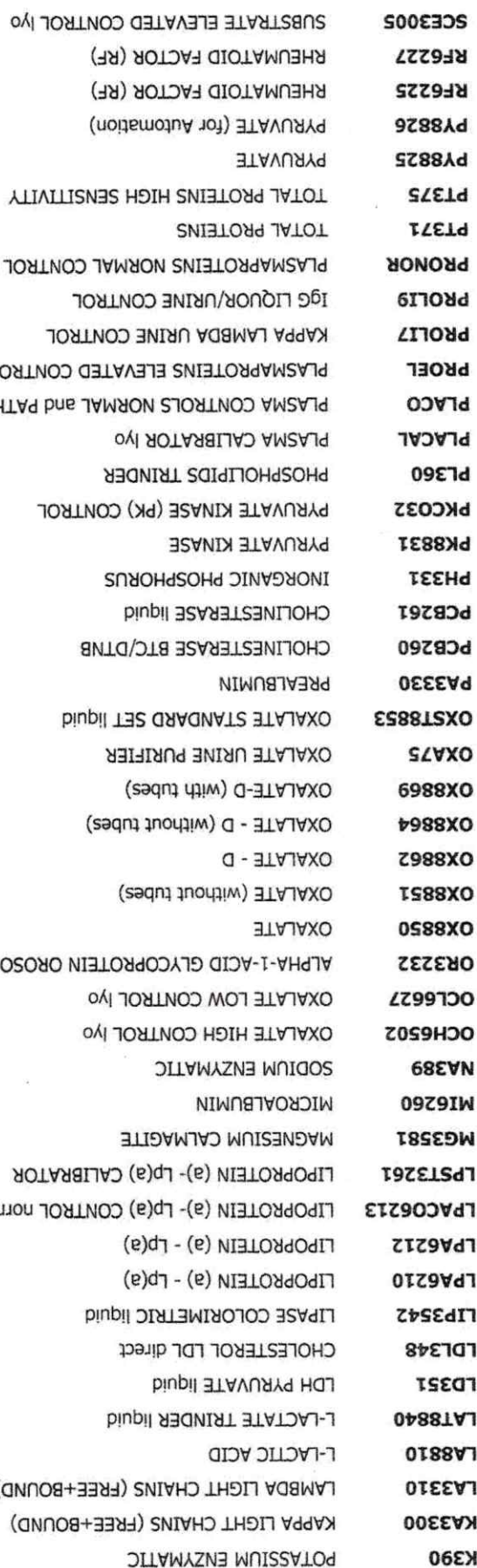
BEN S.M. BIOCHEMICAL ENTERPRISE - a socio unitate
VIA PLOTESEI, 4 - 20127 MARIANA - NAV - TEL +38 0228712393 - FAX +38 022890653
WWW.BEN.BY - INFO@BEN.BY - CASIERIE SOCIALE 06100000 INT.1585
CFR/PLVA 0733300197 R.L. N.1333334 TRIBUNALU BUCURESTI (REDA)

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 FERRENE	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
FEC06204	FERRITIN CONTROL normal/elevated	2x2 mL	+	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 - HYDROXYBUTYRIC ACID (β -HBA)	10	x	10 mL
HBCH3511	β -HBA HIGH CONTROL lvo	6	x	1 mL
HBCL2511	β -HBA LOW CONTROL lvo	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 lvo	3	x	1 mL
HDLD628	CHOLESTEROL HDL/LDL CONTROL lvo	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
IGEC06259	IMMUNOGLOBULIN E (IgE) CONTROL normal/elevated	2x2 mL	+	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



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BEN S.p.A. BIOCHEMICAL ENTERPRISE - a socio unico
Via Piosselli, 4 - 20127 Milano - Italy - Tel. +39 02 871 82 81/3 - Fax: +39 02 88 00 33
www.ben.it - info@ben.it - central@ben.it - info@ben.it
CFRIVA 07351500157 R.U. N.1292314 TRIB. MILANO - COD. FISC. N. 1256315 (REDA)



SCL3006	SUBSTRATE LOW CONTROL lyo	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
THEM0395	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
ZINC069	ZINC LOW and ELEVATED CONTROLS	1x5 mL	+	1x 5 mL

