



Imposta di
bollo assolta

Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI
E DEL SERVIZIO FARMACEUTICO
UFFICIO 4 DGDMF DISPOSITIVI MEDICO DIAGNOSTICI IN VITRO

DGDMF/4/P/I.5.1.e.2/2018/90

VISTA la direttiva 98/79/CE relativa ai dispositivi medico-diagnostici in vitro;

VISTO il D.lgs. n. 332/2000 recante attuazione della direttiva 98/79/CE;

VISTA l'istanza datata 30-05-2018 presentata dalla ditta BPC BioSed s.r.l. con sede legale e sede produttiva in Traversa del Grillo, Km. 0,600 -00060- Castelnuovo di Porto (Roma), Italia, C.F. 07732700583, P.IVA 01854651005;

CONSIDERATO che la ditta istante ha effettuato i versamenti richiesti dal D.M. 07 Agosto 2012;

VISTI gli atti d'ufficio;

HAVING REGARD to 98/79/EC directive concerning the in vitro diagnostic medical devices;

HAVING REGARD to legislative Decree (D.lgs.) n. 332/2000 reporting the accomplishment of 98/79/EC Directive;

HAVING REGARD to the request dated 30-05-2018 submitted by the company BPC BioSed s.r.l. with registered place of business and operative site in Traversa del Grillo, Km. 0,600 -00060- Castelnuovo di Porto (Roma), Italia, C.F. 07732700583, P.IVA 01854651005;

WHEREAS this company paid the fees required by Ministerial Decree (D.M.) August 07, 2012;

HAVING REGARD to the official deeds;

SI ATTESTA

IT IS ATTESTED

che la ditta BPC BioSed s.r.l. con sede legale e sede produttiva in Traversa del Grillo, Km. 0,600 -00060- Castelnuovo di Porto (Roma), Italia, C.F. 07732700583, P.IVA 01854651005 è il fabbricante e ha marcato CE, come dispositivi medico-diagnostici in vitro, secondo le procedure previste dalla direttiva 98/79/CE, i seguenti prodotti:

that the company BPC BioSed s.r.l. with registered place of business and operative site in Traversa del Grillo, Km. 0,600 -00060- Castelnuovo di Porto (Roma), Italia, C.F. 07732700583, P.IVA 01854651005 is the manufacturer and affixed CE marking as in vitro diagnostic medical devices, according to the Directive 98/79/EC, to the following products:

ALBUMIN	R1033	R1 2 x 250 ml	Std 1 x 5 ml
	KR8003	R1 5 x 40 ml	Std 1 x 5 ml
	G2004	R1 6 x 45 ml	
ALKALINE PHOSPHATASE	R1195	R1 4 x 40 ml	R2 1 x 40 ml
	KR2025	R1 4 x 32 ml	R2 4 x 8 ml
	G2028	R1 6 x 32 ml	R2 6 x 8 ml
	G4001	R1 6 x 40 ml	R2 2 x 30 ml

AMYLASE CNPG3 Liquid	R1053 KR8005 G2006-B	R1 4 x 50 ml R1 5 x 40 ml R1 3 x 45 ml	
DIRECT BILIRUBIN HF	R1056 KR2032 G2009	R1 2 x 200 ml R1 5 x 30 ml R1 5 x 40 ml	R2 1 x 40 ml R2 1 x 18 ml R2 1 x 15 ml
TOTAL BILIRUBIN DMSO	R1055 KR2018 G2023	R1 2 x 200 ml R1 5 x 30 ml R1 5 x 40 ml	R2 1 x 40 ml R2 1 x 8 ml R2 1 x 15 ml
CALCIUM FAST	R1083 KR8008 G2021	R1 2 x 50 ml R1 2 x 40 ml R1 3 x 45 ml	R2 2 x 50 ml Std 1 x 5 ml R2 2 x 40 ml R2 3 x 45 ml
CALCIUM AZ	R1085 KR8006 G2022 G2022-B	R1 4 x 50 ml R1 5 x 40 ml R1 6 x 45 ml R1 3 x 45 ml	
CHLORIDES H.F.	R1094 G2016 KR8015	R1 4 x 50 ml Std 1 x 5 ml R1 6 x 45 ml R1 5 x 40 ml	
CHOLESTEROL F.X.	R1120 R1118 KR8017 G2018	R1 4 x 50 ml R1 2 x 250 ml R1 5 x 40 ml R1 6 x 45 ml	Std 1 x 5 ml Std 1 x 5 ml
HDL Cholesterol	R1124 KR2028 G2041-B G4020	R1 1 x 60 ml R1 4 x 30 ml R1 3 x 30 ml R1 6 x 30 ml	R2 1 x 20 ml R2 4 x 10 ml R2 3 x 10 ml R2 2 x 30 ml
LDL Cholesterol	R1119 G2025-B G4044	R1 1 x 30 ml R1 3 x 30 ml R1 6 x 30 ml	R2 1 x 10 ml R2 1 x 10 ml R2 2 x 30 ml
CHOLINESTERASE	R1128	R1 20 x 3 ml	
CK-MB	R1036 R1035 G2013-B G4006	R1 4 x 20 ml R1 1 x 20 ml R1 3 x 32 ml R1 6 x 40 ml	R2 1 x 20 ml R2 1 x 5 ml R2 3 x 8 ml R2 2 x 30 ml
CK-NAC	R1164 R1164-B KR8013 G2014-B G4005	R1 4 x 40 ml R1 4 x 20 ml R1 4 x 32 ml R1 3 x 32 ml R1 6 x 40 ml	R2 1 x 40 ml R2 1 x 20 ml R2 4 x 8 ml R2 3 x 8 ml R2 2 x 30 ml
CREATININE H.F.	R1140 KR2020 G2082	R1 1 x 250 ml 1 x 5 ml R1 2 x 40 ml R1 3 x 45 ml	R2 1 x 250 ml Std R2 2 x 40 ml R2 3 x 45 ml
GAMMA-GT	R1248 R1243 KR2029 G2032 G4004	R1 4 x 40 ml R1 4 x 20 ml R1 4 x 32 ml R1 6 x 32 ml R1 6 x 40 ml	R2 1 x 40 ml R2 1 x 20 ml R2 4 x 8 ml R2 6 x 8 ml R2 2 x 30 ml
GLICATED HEMOGLOBIN (HBA1c) DIRECT ENZYMATIC	R1153 G2005	R1 1 x 30 ml R1 3 x 45 ml	R2 1 x 10 ml R2 3 x 15 ml
LYSING AGENT Dilution Ratio Sample/R 1:50. Ready in 5'	R1152L	R1 1 x 125 ml	
GLUCOSE F.X.	R1250 R1253 KR2031 G2034	R1 2 x 250 ml R1 4 x 50 ml R1 5 x 40 ml R1 6 x 45 ml	Std 1 x 5 ml Std 1 x 5 ml
GOT-AST Liquid	R1276 KR2033 G2038 G4009	R1 4 x 40 ml R1 4 x 32 ml R1 6 x 32 ml R1 4 x 30 ml	R2 1 x 40 ml R2 4 x 8 ml R2 6 x 8 ml R2 2 x 30 ml

GPT-ALT Liquid	R1286 KR2035 G2042 G4007	R1 4 x 40ml R1 4 x 32 ml R1 6 x 32 ml R1 4 x 30 ml	R2 1 x 40 ml R2 4 x 8 ml R2 6 x 8 ml R2 2 x 30ml
IRON Ferene EXTRA	KR2017	R1 3 x 40 ml Std 1x 5 ml	R2 1 x 9 ml R3 1 x 5 ml
IRON FERENE	R1086 G2033 G4010	R1 2 x 125 ml Std 1x 5 ml R1 3 x 40 ml Std 1x 5 ml	R2 1 x 10 ml 1 x 5 ml R2 3 x 9 ml R3 1 x 3 ml Std 1x 5 ml
LDH-p	R1291 R1293 KR2037 G2044-B G4013	R1 4 x 40ml R1 4 x 20 ml R1 4 x 32 ml R1 3 x 32 ml R1 6 x 30 ml	R2 1 x 40 ml R2 1 x 20 ml R2 4 x 8 ml R2 3 x 8 ml R2 2 x 30 ml
LIPASE	R1312 KR2024 G2080 G4015	R1 1 x 40ml R1 3 x 30 ml R1 4 x 30 ml R1 6 x 30 ml	R2 1 x 8 ml R2 3 x 6 ml R2 4 x 6 ml R2 2 x 18 ml
MAGNESIUM CALMAGITE	R1344 KR2040 G2047	R1 4 x 50 ml R1 5 x 40 ml R1 6 x 45 ml	Std 1 x 5 ml
PHOSPHORUS UV	R1232 KR2027 G2030	R1 2 x 250 ml R1 5 x 40 ml R1 6 x 45 ml	Std 1x 5 ml
POTASSIUM Enzymatic	R1365 G2084	R1 1 x 40 ml R1 6 x 32 ml	R2 1 x 10 ml R2 6 x 8 ml Std 2 x 3 ml
TOTAL PROTEIN H.F.	R1354 KR2043 G2050	R1 2 x 250 ml R1 5 x 40 ml R1 6 x 45 ml	Std 1 x 5ml
URINARY PROTEIN	R1353 KR2046 G2053	R1 4 x 50 ml R1 4 x 30 ml R1 3 x 40 ml	R2 1 x 20 ml R2 1 x 12 ml R2 1 x 12 ml Std 1 x 5 ml Std 1 x 5 ml Std 1 x 5 ml
SODIUM ENZYMATIC	R1362 G2085	R1 1 x 20 ml R1 6 x 30 ml	R2 1 x 10 ml R2 6 x 15 ml Std 2 x 3 ml
TRIGLYCERIDES	R1373 KR2047 G2054	R1 4 x 50 ml R1 5 x 40 ml R1 6 x 45 ml	Std 1 x 5 ml
UREA (BUN) UV BI-RGT	R1415 KR8019 G2007 G4017	R1 4 x 40 ml R1 4 x 32 ml R1 6 x 32 ml R1 6 x 40 ml	R2 1 x 40 ml R2 4 x 8 ml R2 6 x 8 ml R2 2 x 30 ml Std 1 x 5 ml
URIC ACID L	R1012 KR8001 G2002	R1 4 x 50ml R1 5 x 40 ml R1 6 x 45 ml	Std 1 x 5 ml
Reaction Segments	CO0047	100 pcs	
Reagent Containers	CO0051/A	50 pcs	
Serum Cups	CO0049	1000 pcs	

Thermal Printer Paper	CO0039	5 pcs
Pierced Pressure Caps	CO0050F	1000 pcs
Tube with Caps	CO0110PT	100 pcs
Cleaning Agent	CO4010	2 x 250 ml
Extra Cleaning	CO4015	2 x 250 ml
Ipcleaning	CO4020	2 x 250 ml
Reagent's Containers 17ml	CO0053/A	50 pcs
Support 17 ml Containers	CO0056	50 pcs
Reagent containers "C" 60ml	CO0071/A	50 pcs
Reagent containers "A+B" 40+17ml	CO0072/A	50 pcs
Serum cups G240/G4500DR	CO0080	1000 pcs
Serum cups Junior/G4500DR/7500DR	CO0058	1000 pcs
Calibrators		
Multicalibrator E	C2039	10x5 ml
Multicalibrator	95015	10x5 ml
Multicalibrator E	C2036ER	10x3 ml
HBA1c Calibrator	C2052	4 x 0.5 ml
HDL/LDL/CK-MB Calibrator Cal	C2032	3x1 ml
	95506	2x2 ml
Potassium Cal	C2057	2 x 3 ml
Sodium Cal	C2055	2 x 3 ml
Controls		
Eurocontrol N	C2012	10x5 ml
Exatrol N Level 1	95010	10x5 ml
Eurocontrol P	C2022	10x5 ml
	95011	10x5 ml
IIBA1c Control	C2053	4x0.5 ml
HDL/LDL / CK-Nac / CK-MB Control level 1	95516	2x2 ml
HDL/LDL / CK-Nac / CK-MB Control level 2	95526	2x2 ml
Uric Acid std	C3051	3x5 ml
Albumin std	C3091	3x5 ml
Calcium std	C3094	3x5 ml
Chlorides std	C3095	3x5 ml
Cholesterol std	C3096	3x5 ml
Cholesterol std	C3071	3x5 ml
Creatinine std	C3098	3x5 ml
Iron std	C3065	3x5 ml
Fructosamine std	C3100	3x5 ml
Phosphorus std	C3101	3x5 ml
Magnesium std	C3102	3x5 ml
Potassium ISE std	C3103	3x5 ml
Total Protein std	C3104	3x5 ml
Urinary Protein std	C3105	3x5 ml
Urea std	C3107	3x5 ml
Triglycerides std	C3108	3x5 ml

Antistreptolysin (ASO)	T2004 G2063	1x25 ml; 1x5 ml 3x30 ml
Antithrombin III	T2005 G2083	1x25 ml; 1x5 ml 3x30 ml
C-Reactive Protein (CRP)	T2006 G2079	1x25 ml; 1x5ml 3x30 ml
IgA	T2011 G2071	1x25 ml; 1x5 ml 3x30 ml
IgG	T2013 G2073	1x25 ml; 1x5 ml 3x30 ml
IgM	T2015 G2075	1x25 ml; 1x5 ml 3x30 ml
Rheumatoid Factor	T2036 G2060-B	1x25 ml; 1x5 ml 3x30ml
Transferrin	T2037 G2077	1x25 ml; 1x5 ml 3x30 ml
Alpha 1 Acid Glycoprotein	T2001 G2065	1x25 ml; 1x5 ml 3x30 ml
Multical for Immunturbidimetry	CT1950	1x1 ml
C-Reactive Protein Standard High	CT1970	1x1 ml
C-Reactive Protein Standard Low	CT1971	1x1 ml
Rheumatoid Factor Standard High	CT1985	1x1 ml
Antistreptolysin Standard High	CT1988	1x1 ml
C-Reactive Protein Control High	CT1983	1x1 ml
C-Reactive Protein Control Low	CT1984	1x1 ml
Rheumatoid Factor (RF) Control	CT1992	1x1 ml
Anti-Streptolysin Control	CT1994	1x1 ml
Descrizione	Rif	Formato Kit
Reagent pack (High Volume)	G2081	
Cleaning solution	G2058/A	1x90 ml
Electrode "Na"	5201	1 pz
Electrode "K"	5202	1 pz
Electrode Reference	5204	1 pz
Spacer Electrode	5206	1 pz
Electrode "Cl"	5207	1 pz
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GLOBAL 240	19-0000	
GLOBAL 720	19-G720	
GLOBAL 4500DR	22-0000	
GLOBAL 7500DR	22-G7500DR	

I suddetti prodotti, in base all'art. 4 della direttiva 98/79/CE, sono di libera circolazione e possono essere messi in commercio in Italia e in tutto il territorio dell'Unione Europea.

Si rilascia il presente attestato su richiesta dell'interessato per gli usi consentiti dalla legge e per l'esportazione.

The above mentioned products, according to the art. 4 of 98/79/EC directive, can freely circulate and can be commercialized in Italy and in the whole of the European Union.

This certificate is issued on the interested company's request according to the law and for exporting.



DIRETTORE DELL'UFFICIO
THE OFFICE DIRECTOR

Dr. Mauro Dionisio

(Signature)