



Beckman Coulter Biomedical Limited.
Lismeehan,
O'Callaghan's Mills,
Co. Clare,
Ireland.
Tel. +353-65-6831100.
Fax: +353-65-6831122.

DECLARATION OF CONFORMITY

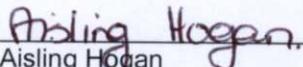
To Whom it May Concern:

I, **AISSLING HOGAN**, Quality System Administrator at Beckman Coulter Biomedical Limited hereby on behalf of the Company do solemnly declare that:

1. Beckman Coulter Biomedical Limited with offices at Lismeehan, O'Callaghan's Mills, County Clare, Ireland has its registered business address at Arthur Cox Building, Earlsfort Terrace, Dublin 2, Ireland.
2. The Beckman Coulter Product range of reagents, calibrators and controls (as per Appendix 1 attached) is legally manufactured:
 - By: Beckman Coulter, Inc. 250 S. Kraemer Blvd. Brea, CA 92822, USA.
 - Authorised Representative: Beckman Coulter Biomedical Limited with offices at Lismeehan, O'Callaghan's Mills, County Clare, Ireland.
3. Beckman Coulter Biomedical Limited is now operating under the following legislation and the Beckman Coulter product range and associated consumables fully comply with the requirements of the said legislation:

(i) EC Directive 98/79/EC In-Vitro Diagnostic Medical Devices.
4. Beckman Coulter Biomedical Limited has CE marked its products range of reagents, calibrators and controls (as per Appendix 1 attached) and labelled them as such.

Declared and signed by **AISSLING HOGAN** on this 14th day of April 2010.


Aisling Hogan
Quality System Administrator

APPENDIX 1

CAT. NO.	PARAMETER
65164	CELLULOSE ACETATE FILM HITE SYSTEM FRACTOSCAN
O9100414	CELLULOSE ACETATE FILM HITE SYSTEM
ODC0003	CONTROL SERUM 1
ODC0004	CONTROL SERUM 2
ODC0005	HDL/LDL-CHOLESTEROL CONTROL SERUM
ODC0006	DAU MULTI-DRUG CONTROL
ODC0007	DAU SPECIALITY CONTROL
ODC0008	DAU THC 25 CONTROL
ODC0009	DAU THC 50 CONTROL
ODC0011	HDL-CHOLESTEROL CALIBRATOR
ODC0012	LDL-CHOLESTEROL CALIBRATOR
ODC0013	CRP (LATEX) CONTROL SERUM
ODC0014	ITA CONTROL SERUM LEVEL 1
ODC0015	ITA CONTROL SERUM LEVEL 2
ODC0016	ITA CONTROL SERUM LEVEL 3
ODC0019	BICARBONATE CALIBRATOR
ODC0022	HbA1c CONTROL
ODC0023	HDL CHOLESTEROL CALIBRATOR
ODC0024	LDL CHOLESTEROL CALIBRATOR
ODC0025	URINE CALIBRATOR
ODC0026	CRP LATEX CALIBRATOR NORMAL SET
ODC0027	CRP LATEX CALIBRATOR HIGHLY SENSITIVE SET
ODC0028	RF LATEX CALIBRATOR
ODC0029	D-DIMER CONTROL
ODC00032	CRP CALIBRATOR
ODC6314	DAU NEGATIVE CALIBRATOR
ODC6315	DAU PRIMARY CUT-OFF MULTI-DRUG CALIBRATOR
ODC6316	DAU SECONDARY CUT-OFF MULTI-DRUG CALIBRATOR
ODC6317	DAU INTERMEDIATE CUT-OFF MULTI-DRUG CALIBRATOR
ODC6318	DAU HIGH CUT-OFF MULTI-DRUG CALIBRATOR
ODC6319	DAU METHADONE CUT-OFF CALIBRATOR
ODC6320	DAU METHADONE INTERMEDIATE CALIBRATOR
ODC6321	DAU METHADONE HIGH CALIBRATOR
ODC6322	DAU THC 25 CALIBRATOR
ODC6323	DAU THC 50 CALIBRATOR
ODC6324	DAU THC 75 CALIBRATOR
ODC6325	DAU THC 100 CALIBRATOR
ODC6326	DAU LOW INTERMEDIATE MULTI-DRUG CALIBRATOR
ODC6403	DIGITOXIN CALIBRATOR
ODC6404	DIGOXIN CALIBRATOR
ODC6411	CORE TDM MULTI-CALIBRATOR
ODC6413	ANTIBIOTIC TDM MULTI-CALIBRATOR

APPENDIX 1

CAT. NO.	PARAMETER
ODR2000	WASH SOLUTION
ODR2041	CK-MB CONTROL SERUM
ODR20067	CLEANING SOLUTION (FOR CONTAMINATION AVOIDANCE)
ODR3005	APO A1 & B CALIBRATOR
ODR3013	ASO CALIBRATOR
ODR3021	SERUM PROTEIN MULTI-CALIBRATOR 1
ODR3022	APO A1 & B CALIBRATOR
ODR3023	SERUM PROTEIN MULTICALIBRATOR 2
ODR3024	MICROALBUMIN CALIBRATOR
ODR3025	MYOGLOBIN CALIBRATOR
ODR3029	PREALBUMIN CALIBRATOR
ODR3032	HbA1c CALIBRATOR
ODR3033	D-DIMER CALIBRATOR
ODR30034	CK-MB CALIBRATOR
ODR30037	MC CAL A
ODR30035	CK-MB CONTROL SERUM LEVEL 1
ODR30036	CK-MB CONTROL SERUM LEVEL 2
OE60100	PYRIDOXAL PHOSPHATE (P5P) TABLET
OE60106	PYRIDOXAL PHOSPHATE (P5P) LIQUID
OE60265	BUFFER SOLUTION
OE60266	BUFFER SOLUTION (NT)
OE61094	STAINING SOLUTION
OE61101	DESTAINING SOLUTION
OE61105	TRANSPARENCY SOLUTION
OE61106	TRANSPARENCY SOLUTION
OE65160	BUFFER SOLUTION
OE65161	STAINING SOLUTION
OE65162	DESTAINING SOLUTION
OE65163	TRANSPARENCY SOLUTION
OE66039	CLEANING SOLUTION
OE66300	SYSTEM CALIBRATOR
OE66313	ISE Na+/K+ SELECTIVITY CHECK
OE66314	ISE INTERNAL REFERENCE
OE66315	ISE LOW/HIGH URINE STANDARD
OE66316	ISE HIGH SERUM STANDARD
OE66317	ISE LOW SERUM STANDARD
OE66318	ISE REFERENCE
OE66319	ISE MID STANDARD
OE66320	ISE BUFFER
OSR0001	WASH SOLUTION
OSR0004	HEMOGLOBIN DENATURANT
OSR6004	ALP

APPENDIX 1

CAT. NO.	PARAMETER
OSR6006	alpha - AMYLASE
OSR6007	ALT
OSR6009	AST
OSR6020	GGT
OSR6033	TRIGLYCERIDES
OSR6036	URIC ACID
OSR6098	URIC ACID
OSR6101	ACP
OSR6102	ALBUMIN
OSR6103	ALP
OSR6104	ALP
OSR6106	alpha - AMYLASE
OSR6107	ALT
OSR6109	AST
OSR6111	DIRECT BILIRUBIN
OSR6112	TOTAL BILIRUBIN
OSR6113	CALCIUM oCPC
OSR6114	CHOLINESTERASE
OSR6116	CHOLESTEROL
OSR6119	GGT
OSR6120	GGT
OSR6121	GLUCOSE
OSR6122	INORGANIC PHOSPHOROUS
OSR6124	UIBC
OSR6126	LDH
OSR6127	LDH
OSR6128	LDH
OSR6129	HBDH
OSR6130	LIPASE
OSR6132	TOTAL PROTEIN
OSR6133	TRIGLYCERIDES
OSR6134	UREA
OSR6136	URIC ACID
OSR6137	BICARBONATE
OSR6139	CREATININE
OSR6140	GLUCOSE - STAT
OSR6141	UREA STAT
OSR6142	APO A1
OSR6143	APO B
OSR6144	IgA
OSR6145	IgG
OSR6146	IgM

APPENDIX 1

CAT. NO.	PARAMETER
OSR6147	CRP
OSR6150	FERRITIN
OSR6151	beta-2-MICROGLOBULIN
OSR6152	TRANSFERRIN
OSR6153	CK-MB
OSR6159	C3
OSR6160	C4
OSR6162	alpha-1-ACIDGLYCOPROTEIN
OSR6163	alpha-1-ANTITRYPSIN
OSR6164	CERULOPLASMIN
OSR6165	HAPTOGLOBIN
OSR6167	MICROALBUMIN
OSR6168	MYOGLOBIN
OSR6170	URINARY / CSF PROTEIN
OSR6175	PREALBUMIN
OSR6176	CALCIUM ARSENAZO III
OSR6178	CREATININE
OSR6179	CK (NAC)
OSR6182	alpha-AMYLASE
OSR6183	LDL-CHOLESTEROL
OSR6186	IRON
OSR6187	HDL-CHOLESTEROL
OSR6189	MAGNESIUM
OSR6190	BICARBONATE
OSR6192	HbA1c (HEMOGLOBIN A1c)
OSR6193	LACTATE
OSR6194	ASO
OSR6195	HDL-CHOLESTEROL
OSR6196	LDL-CHOLESTEROL
OSR6197	CHOLESTEROL
OSR6198	URIC ACID
OSR6199	CRP LATEX
OSR6202	ALBUMIN
OSR6204	ALP
OSR6209	AST
OSR6211	DIRECT BILIRUBIN
OSR6212	TOTAL BILIRUBIN
OSR6213	CALCIUM oCPC
OSR6216	CHOLESTEROL
OSR6219	GGT
OSR6221	GLUCOSE
OSR6222	INORGANIC PHOSPHOROUS

APPENDIX 1

CAT. NO.	PARAMETER
OSR6227	LDH
OSR6230	LIPASE
OSR6232	TOTAL PROTEIN
OSR6234	UREA
OSR6236	URIC ACID
OSR6237	BICARBONATE
OSR6270	URINARY / CSF PROTEIN
OSR6276	CALCIUM ARSENAZO III
OSR6279	CK (NAC)
OSR6283	LDL-CHOLESTEROL
OSR6286	IRON
OSR6287	HDL-CHOLESTEROL
OSR6290	BICARBONATE
OSR6295	HDL-CHOLESTEROL
OSR6296	LDL-CHOLESTEROL
OSR6298	URIC ACID
OSR6299	CRP LATEX
OSR6315	BARBITURATES
OSR6316	BENZODIAZEPINES
OSR6317	COCAINE
OSR6318	EDDP
OSR6319	METHADONE
OSR6320	OPIATES
OSR6322	THC
OSR6323	AMPHETAMINES/ECSTASY
OSR6403	DIGITOXIN
OSR6404	DIGOXIN
OSR6411	PHENYTOIN
OSR6412	THEOPHYLLINE
OSR6413	PHENOBARBITAL
OSR6414	CARBAMAZEPINE
OSR6415	VALPROIC ACID
OSR6420	GENTAMYCIN
OSR6504	ALP
OSR6507	ALT
OSR6509	AST
OSR6511	DIRECT BILIRUBIN
OSR6512	TOTAL BILIRUBIN
OSR6516	CHOLESTEROL
OSR6520	GGT
OSR6521	GLUCOSE
OSR6534	UREA

CE Marked Product Listing April 2010

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APPENDIX 1

CAT. NO.	PARAMETER
OSR6536	URIC ACID
OSR6537	BICARBONATE
OSR6541	UREA STAT
OSR6576	CALCIUM ARSENAZO III
OSR6578	CREATININE
OSR6587	HDL-CHOLESTEROL
OSR6602	ALBUMIN
OSR6607	ALT
OSR6621	GLUCOSE
OSR6632	TOTAL PROTEIN
OSR6633	TRIGLYCERIDES
OSR6634	UREA
OSR6678	CREATININE
OSR6698	URIC ACID
OSR60117	CALCIUM ARSENAZO III
OSR60118	TRIGLYCERIDE
OSR60135	D-DIMER
OSR61105	RF LATEX
OSR61117	CALCIUM ARSENAZO III
OSR61118	TRIGLYCERIDE
OSR61138	FERRITIN
OSR61155	CK-MB
OSR61157	CRP
OSR61171	IgA
OSR61172	IgG
OSR61173	IgM
OSR61177	HbA1c APT
OSR61181	DIRECT BILIRUBIN
OSR61202	PARACETAMOL
OSR61203	FERRITIN
OSR61204	CREATININE (ENZYMATIC)
OSR61205	UIBC
OSR60180	P5P
OSR62166	LIH
OSR65117	CALCIUM ARSENAZO III
OSR66100	URINE TOX CREATININE
OSR66118	TRIGLYCERIDE



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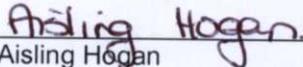
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 - Authorised Representative: Beckman Coulter Biomedical Limited with offices at Lismeehan, O'Callaghan's Mills, County Clare, Ireland.
3. The Beckman Coulter Product range of instruments (as per attachment 2) is legally manufactured:
 - By: Beckman Coulter Biomedical Limited with offices at Arthur Cox Building, Earlsfort Terrace, Dublin 2, Ireland.
4. Beckman Coulter Biomedical Limited is now operating under the following legislation and the Beckman Coulter instruments fully comply with the requirements of the said legislation:
 - (i) **EC Directive 98/79/EC In-Vitro Diagnostic Medical Devices.**
5. Beckman Coulter Biomedical Limited has CE marked its products range of accessories (as per attachment 1 and 2 attached) and labelled them as such.

Declared and signed by **AISLING HOGAN** on this 14th day of April 2010.


Aisling Hogan
Quality System Administrator



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ATTACHMENT 1

CAT. NO.	PARAMETER
AU400	Automated Clinical Chemistry Analyser
AU480	Automated Clinical Chemistry Random Access Analyser
AU640	Automated Clinical Chemistry Analyser
AU680	Automated Clinical Chemistry Analyser
AU2700	Automated Chemistry Analyser
AU2700Plus	Automated Clinical Chemistry Random Access Analyser
AU3000i	Automated Immunoassay Analyser
AU5400	Automated Clinical Chemistry Analyser
HTE320	Automated Integrated Electrophoresis System
PK7200	Automated Pre-Transfusion Analyser and Consumables
PK7300	Automated Pre-Transfusion Analyser and Consumables
OE63100	Na
OE63101	Cl
OE63102	REF
OE63103	K



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ATTACHMENT 2

CAT. NO.	PARAMETER
AU400 S/N 7	Automated Clinical Chemistry Analyser
AU600IVD	Automated Clinical Chemistry Random Access Analyser
AU640 S/N 7	Automated Clinical Chemistry Analyser
AU2700 S/N 7	Automated Chemistry Analyser