

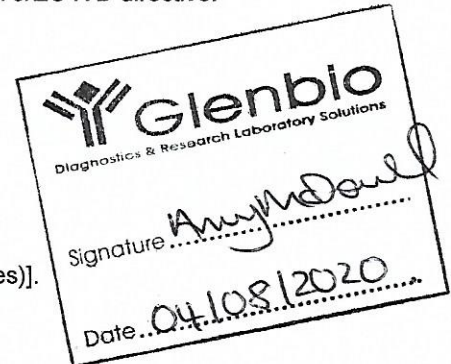
To whom it may concern,

I hereby certify that the following products are classified as 'General IVD's' in accordance with the 98/79/EC IVD directive. The products will be supplied with a CE mark and are categorised as Annex III of the 98/79/EC IVD directive.

Manufacturer: Glenbio Ltd.
10 Kilbegs Road
Antrim
Co. Antrim
BT41 4NN
United Kingdom

Classification: General category in-vitro diagnostic medical device.
[Other Device (all devices except Annex II and self-testing devices)].

Product List:



ACETAMINOPHEN/PARACETAMOL	b-HYDROXYBUTYRATE
ACID PHOSPHATASE	B-HYDROXYBUTYRATE CALIBRATOR
ACID WASH SOLUTION	BICARBONATE
ADA CALIBRATOR	BICARBONATE CALIBRATOR
ADA CONTROL LEVEL 1	BICARBONATE CONTROL
ADA CONTROL LEVEL 2	BILIRUBIN DIRECT DPD
ADENOSINE DEAMINASE (ADA)	BILIRUBIN DIRECT VANADATE
ALANINE AMINOTRANSFERASE (ALT)	BILIRUBIN TOTAL DPD
ALBUMIN BCG	BILIRUBIN TOTAL VANADATE
ALBUMIN BCP	C3
ALCOHOL	C4
ALCOHOL CALIBRATOR	CALCIUM ARSENAZO III
ALCOHOL CONTROL SET	CALCIUM CPC
ALKALINE PHOSPHATASE (ALP) AMP	CALPROTECTIN
ALKALINE PHOSPHATASE (ALP) DEA	CALPROTECTIN CALIBRATOR SET
ALKALINE PHOSPHATASE (ALP) DGKC	CALPROTECTIN CONTROL SET
ALKALINE WASH SOLUTION	CALPROTECTIN SAMPLE DILUTION VIALS
ALPHA-1-ANTITRYPSIN	CERTUS 450 ANALYSER
ALPHA-HYDROXYBUTYRATE DEHYDROGENASE (a-HBDH)	CERULOPLASMIN
AMMONIA	CHOLESTEROL
AMMONIA CONTROL SET	CHOLINESTERASE
AMYLASE CNPG3	CK-MB
AMYLASE EPS	CK-MB CALIBRATOR
AMYLASE IFCC	CK-MB CONTROL
ANGIOTENSIN CONVERTING ENZYME (ACE)	CK-NAC
ANGIOTENSIN CONVERTING ENZYME (ACE) CALIBRATOR	CLEANING SOLUTION
ANGIOTENSIN CONVERTING ENZYME (ACE) CONTROL LEVEL 1	COPPER
ANGIOTENSIN CONVERTING ENZYME (ACE) CONTROL LEVEL 2	C-REACTIVE PROTEIN (CRP)
ANTI-BACTERIAL SOLUTION 50	C-REACTIVE PROTEIN (CRP) FULL RANGE
ANTISTREPTOLYSIN O (ASO)	CREATININE ENZYMATIC
ANTISTREPTOLYSIN O (ASO) CONTROL LEVEL 1	CREATININE JAFFE
ANTISTREPTOLYSIN O (ASO) CONTROL LEVEL 2	CRP CALIBRATOR
APO A&B CALIBRATOR	CRP CONTROL LEVEL 1
APOLIPOPROTEIN A-1 (APO A1)	CRP CONTROL LEVEL 2
APOLIPOPROTEIN B (APO B)	CYSTATIN C
ASO CALIBRATOR	CYSTATIN C CALIBRATOR
ASPARTATE AMINOTRANSFERASE (AST)	CYSTATIN C CONTROL SET
AU SERIES SYSTEM W1 SOLUTION	FERRITIN
AU SERIES SYSTEM W2 ACID SOLUTION	FERRITIN CALIBRATOR
AU SERIES SYSTEM W2 ALKALINE SOLUTION	FERRITIN CONTROL SET
AU SERIES SYSTEM WASH SOLUTION	FIBRINOGEN
BECKMAN OLYMPUS ISE BUFFER	FIBRINOGEN CALIBRATOR
BECKMAN OLYMPUS ISE CLEANING SOLUTION	FIBRINOGEN CONTROL SET
BECKMAN OLYMPUS ISE HIGH SERUM STANDARD	FOB
BECKMAN OLYMPUS ISE HIGH/LOW URINE STANDARD	FOB CALIBRATOR
BECKMAN OLYMPUS ISE INTERNAL REFERENCE SOLUTION	FOB CONTROL SET
BECKMAN OLYMPUS ISE LOW SERUM STANDARD	FOB SAMPLE DILUTION VIALS
BECKMAN OLYMPUS ISE MID STANDARD	FRUCTOSAMINE
BECKMAN OLYMPUS ISE REFERENCE	FRUCTOSAMINE CALIBRATOR
BECKMAN OLYMPUS Na/K SELECTIVITY CHECK SOLUTION	FRUCTOSAMINE CONTROL LEVEL 1

G6PDH	MULTI-CLEAN NaHO-D
G6PDH CALIBRATOR	PANCREATIC AMYLASE
G6PDH CONTROL	PARACETAMOL CALIBRATOR
GAMMA GT	PARACETAMOL CONTROL SET
GENERAL CHEMISTRY CALIBRATOR	PHOSPHOROUS
GENERAL CHEMISTRY CONTROL LEVEL 1	POTASSIUM
GENERAL CHEMISTRY CONTROL LEVEL 2	POTASSIUM CALIBRATOR
GLUCOSE HEX	PREALBUMIN
GLUCOSE PAP	PROCALCITONIN
H.S.CRP CONTROL LEVEL 1	PROCALCITONIN CALIBRATOR
H.S.CRP CONTROL LEVEL 2	PROCALCITONIN CONTROL
HAPTOGLOBIN	REF. ELEC. SOL.
HBA1C	RF CALIBRATOR
HBA1C CONTROL	RF CONTROL LEVEL 1
HbA1C ENZYMATIC	RF CONTROL LEVEL 2
HBA1C ENZYMATIC CALIBRATOR	RHEUMATOID FACTOR (RF)
HBDH DGKC	SALICYLATE
HDL CHOLESTEROL DIRECT	SALICYLATE (ENZYMATIC) CALIBRATOR
HDL/LDL CALIBRATOR	SALICYLATE (KELLER) CALIBRATOR
HIGH SENSITIVITY C-REACTIVE PROTEIN (HsCRP)	SALICYLATE (KELLER) CONTROL
HITERGENT	SALICYLATE ENZYMATIC
HOMOCYSTEINE	SAPPHIRE 800 ACID WASH SOLUTION
HOMOCYSTEINE CALIBRATOR	SAPPHIRE 800 ANALYSER
HOMOCYSTEINE CONTROL SET	SAPPHIRE 800 CS ALKALINE DETERGENT
HsCRP CALIBRATOR	SAPPHIRE 800 DETERGENT SOLUTION
IgA	SAPPHIRE 800 WASH SOLUTION
IgE	SODIUM
IgE CALIBRATOR SET	SODIUM CALIBRATOR
IgE CONTROL	SPECIFIC PROTEIN CALIBRATOR
IgG	SPECIFIC PROTEIN CONTROL LEVEL 1
IgM	SPECIFIC PROTEIN CONTROL LEVEL 2
INT. REF. SOL.	SPECIFIC PROTEIN CONTROL LOW
IRON FERROZINE	STD. HIGH Na/K/Cl
ISE CLEANER (1%)	STD. LOW Na/K/Cl
ISE COMPENSATOR	TOTAL BILE ACIDS
ISE DILUENT	TOTAL BILE ACIDS CALIBRATOR
LACTATE	TOTAL BILIRUBIN O'LEARY
LDH DGKC (P-L)	TOTAL BILIRUBIN VANADATE
LDH IFCC (L-P)	TOTAL PROTEIN
LDH SCE	TRANSFERRIN
LDL CHOLESTEROL DIRECT	TRANSFERRIN CALIBRATOR
LIPASE	TRIGLYCERIDES
LIPID CONTROL LEVEL 1	UREA
LIPID CONTROL LEVEL 2	URIC ACID
LITHIUM	URINARY PROTEIN BENZ CHLORIDE
LITHIUM CONTROL SET	URINARY PROTEIN PYROGALLOL RED
LP(a)	URINE CONTROL LEVEL 1
Lp(a) CALIBRATOR	URINE CONTROL LEVEL 2
MAGNESIUM XYLIDYL BLUE	VITAMIN D
MICROALBUMIN	VITAMIN D CALIBRATOR
MICROALBUMIN CALIBRATOR	VITAMIN D CONTROL SET
MICROALBUMIN CONTROL	ZINC

We hereby declare that the requirements imposed by the IVD Directives 98/79/EC and the Statutory Instruments 2002 No. 618 (Consolidated legislation) have been fulfilled.

Signed

Date



04 Aug 2020

