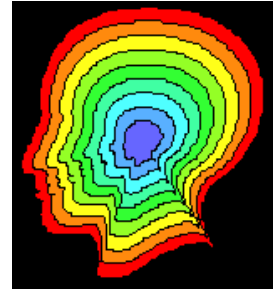


TNMC DEVICES d.o.o

**AUTHORISED REPRESENTATIVE IN
THE EUROPEAN UNION**



CERTIFICATE OF REGISTRATION

REF NO.: TNMC-BR-01-2020

2020-10-20

Manufacturer: Bio Research for Medical Diagnostics

**Address: Muslim AlAttar Street
Northern Marka
P.O. Box: 1235
Amman 11953 Jordan**

TNMC confirms that the aforementioned manufacturer has fulfilled the essential requirements of appointing an European Authorised Representative in accordance with the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices (as amended) and carries the CE-Marking accordingly.

As of 2020-10-20 and as long as the Manufacturer will continue complying with the above mentioned requirements, he may place the devices in the European Community territory.

A ten Napel
Managing Director
TNMC Device d.o.o





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CERTIFICATE OF REGISTRATION — CLASS 1

Chemistry Line			
Product Name	Product Code	Intended use	GMDN Code
Alkaline Phosphatase (SL), DGKC	CZ001	A collection of reagents and other associated materials intended to be used for the quantitative measurement of one or multiple alkaline phosphatase (ALP) isoenzymes in a clinical specimen, using an enzyme spectrophotometry method.	52930
Alpha Amylase (SL), CNPG3	CZ002	A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of one or multiple amylase isoenzymes in a clinical specimen, using an enzyme spectrophotometry method.	59073
ALT/GPT (SL), UV IFCC	CZ003	A collection of reagents and other associated materials intended to be used for the quantitative measurement of alanine aminotransferase (ALT) in a clinical specimen, using an enzyme spectrophotometry method.	52923
AST/GOT (SL), UV IFCC	CZ005	A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of one or multiple aspartate aminotransferase (AST) isoenzymes in a clinical specimen, using an electrophoresis method.	52950
Gamma GT (SL), SZASZ	CZ007	A collection of reagents and other associated materials intended to be used for the quantitative measurement of gamma glutamyl-transferase (GGT) in a clinical specimen, using an enzyme spectrophotometry method.	53027
LDH (SL), SCE	CZ008	A collection of reagents and other associated materials intended to be used for the quantitative measurement of total lactate dehydrogenase (LDH) in a clinical specimen, using an enzyme spectrophotometry method.	53072
Albumin, BCG	CS001	A collection of reagents and other associated materials intended to be used for the quantitative measurement of albumin in a clinical specimen, using a spectrophotometry method.	59071
Bilirubin Direct, JEN-DRASSIK-GROF	CS002	A collection of reagents and other associated materials intended to be used for the quantitative measurement of conjugated (direct) bilirubin in a clinical specimen, using a spectrophotometry method.	53233



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Bilirubin Total, JEN-DRASSIK-GROF	CS003	A collection of reagents and other associated materials intended to be used for the quantitative measurement of total bilirubin in a clinical specimen, using a spectrophotometry method.	53229
Bilirubin Total & Direct, JEN-DRASSIK-GROF	CS004	A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of total and conjugated (direct) bilirubin in a clinical specimen, using a spectrophotometry method	63410
Cholesterol (SL), CHOD-PAP	CS005	A collection of reagents and other associated materials intended to be used for the quantitative measurement of total cholesterol lipid in a clinical specimen, using an enzyme spectrophotometry method.	53359
Creatinine Kinetic, Jaffe Reaction	CS006	A collection of reagents and other associated materials intended to be used for the quantitative measurement of creatinine in a clinical specimen, using a spectrophotometry method.	53251
Glucose (SL), GOD-PAP	CS008	A collection of reagents and other associated materials intended to be used for the quantitative measurement of glucose in a clinical specimen, using an enzyme spectrophotometry method.	53301
HDL Cholesterol, Precipitation	CS009	A collection of reagents and other associated materials intended to be used for the quantitative measurement of high density lipoprotein (HDL) cholesterol lipid in a clinical specimen, using an enzyme spectrophotometry method.	53391
Hemoglobin Reagent (50XConc.) (DRABKIN'S Reagent)	CS010	A substance or reactant intended to be used together with a parent IVD to perform a specific function in an assay that is used for the qualitative and/or quantitative detection of hemoglobin in a clinical specimen.	57273
LDL Cholesterol	CS011	A collection of reagents and other associated materials intended to be used for the quantitative measurement of low density lipoprotein (LDL) cholesterol lipid in a clinical specimen, using an enzyme spectrophotometry method.	53395
Total Protein, Biuret	CS015	A collection of reagents and other associated materials intended to be used for the quantitative measurement of total protein in a clinical specimen, using a spectrophotometry method.	61900



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Triglyceride (SL), GPO-PAP	CS016	A collection of reagents and other associated materials intended to be used for the quantitative measurement of triglycerides in a clinical specimen, using an enzyme spectrophotometry method	53460
Urea (SL) Endpoint-Berthelot	CS017	A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of urea or urea nitrogen [also known as blood urea nitrogen (BUN)] in a clinical specimen, using a spectrophotometry method. It is typically used as an indicator of kidney function and/or to differentiate between prerenal and postrenal azotemia.	63333
Uric Acid (SL), URICASE-Pap	CS018	A collection of reagents and other associated materials intended to be used for the quantitative measurement of uric acid in a clinical specimen, using an enzyme spectrophotometry method.	53583
HDL Cholesterol (D)	CS020	A collection of reagents and other associated materials intended to be used for the quantitative measurement of high density lipoprotein (HDL) cholesterol lipid in a clinical specimen, using an enzyme spectrophotometry method.	53391
Calcium, CRO-SPHTHALEIN	CE001	A collection of reagents and other associated materials intended to be used for the quantitative measurement of calcium (Ca ²⁺) in a clinical specimen, using a spectrophotometry method.	45789
Magnesium, XY-LIDYL Blue	CE002	A collection of reagents and other associated materials intended to be used for the quantitative measurement of magnesium (Mg ²⁺) in a clinical specimen, using a spectrophotometry method.	46795
Phosphorus Test	CE003	A collection of reagents and other associated materials intended to be used for the quantitative measurement of inorganic phosphate (PO ₄ ³⁻) [phosphorus] in a clinical specimen using a spectrophotometry method.	59123
ZINC (Colorimetric Test With 5-Brom-PAPS)	CE004	A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of zinc in a clinical specimen, using a spectrophotometry method.	58259



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Serology Line			
Product Name	Product Code	Intended use	GMDN Code
ASO Latex, Slide Agglutination	SL001	A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of antibodies to streptolysin O enzyme produced by multiple serogroups of beta-haemolytic Streptococcus bacteria (e.g., Group A, C and G) in a clinical specimen within a short period, relative to standard laboratory testing procedures, using an agglutination method. This test is commonly used in the laboratory or in point-of-care	63271
CRP Latex, Slide Agglutination	SL002	A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of C-reactive protein (CRP) in a clinical specimen within a short period, relative to standard laboratory testing procedures, using an agglutination method. CRP is a marker associated with bacterial infection and inflammatory conditions. This test is commonly used in the laboratory or in point-of-care analyses.	63234
RF Latex, Slide Agglutination	SL003	A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of rheumatoid factor immunoglobulins in a clinical specimen, using an agglutination method.	55112
RPR Carbon, Slide Agglutination	SL004	A collection of reagents and other associated materials intended to be used for the qualitative and/or semi-quantitative detection of antigens from Treponema pallidum in a clinical specimen within a short period, relative to standard laboratory testing procedures, using an immunochromatographic test (ICT) method. This test is commonly used in the laboratory or in point-of-care analyses for the rapid detection of infection with Treponema pallidum, the bacteria associated with	51788
D-Dimer latex test	SL012	A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of D-dimer protein in a clinical specimen, using an agglutination method.	47346
Salmonella H Group D Antigen (S. TYPHI H)	SF001	A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of total antibodies to multiple species of Salmonella bacteria in a clinical specimen, using an agglutination method.	51535



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Salmonella H Group D Antigen (S. TYPHI H)	SF001	A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of total antibodies to multiple species of Salmonella bacteria in a clinical specimen, using an agglutination method.	51535
Salmonella H Group A Antigen (S. Para TYPHI AH)	SF002	A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of total antibodies to multiple species of Salmonella bacteria in a clinical specimen, using an agglutination method.	51535
Salmonella H Group B Antigen (S. Para TYPHI BH)	SF003	A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of total antibodies to multiple species of Salmonella bacteria in a clinical specimen, using an agglutination method.	51535
Salmonella H Group C Antigen (S. Para TYPHI CH)	SF004	A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of total antibodies to multiple species of Salmonella bacteria in a clinical specimen, using an agglutination method.	51535
Salmonella O Group D Antigen (S. TYPHI O)	SF005	A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of total antibodies to multiple species of Salmonella bacteria in a clinical specimen, using an agglutination method.	51535
Salmonella O Group A Antigen (S. Para TYPHI AO)	SF006	A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of total antibodies to multiple species of Salmonella bacteria in a clinical specimen, using an agglutination method.	51535
Salmonella O Group B Antigen (S. Para TYPHI BO)	SF007	A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of total antibodies to multiple species of Salmonella bacteria in a clinical specimen, using an agglutination method.	51535
Salmonella O Group C Antigen (S. Para TYPHI CO)	SF008	A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of total antibodies to multiple species of Salmonella bacteria in a clinical specimen, using an agglutination method.	51535
Febrile Positive Control	SF009	A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of total antibodies to multiple species of Salmonella bacteria in a clinical specimen, using an agglutination method.	51535



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Febrile Negative Control	SF010	A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of total antibodies to multiple species of Salmonella bacteria in a clinical specimen, using an agglutination method.	51535
Febrile Antigen Kit comprising 6 specified antigens with positive & negative control (H, AH, BH, O, AO, BO)	SF011	A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of total antibodies to multiple species of Salmonella bacteria in a clinical specimen, using an agglutination method.	51535
BRUCELLA ABORTUS Antigen	SF012	A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of total antibodies to Brucella abortus bacteria in a clinical specimen, using an agglutination method.	63236
BRUCELLA MELITENSIS Antigen	SF013	A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of total antibodies to Brucella melitensis bacteria in a clinical specimen, using an agglutination method.	63239
Bengal Rose	SF015	A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of total antibodies to multiple species of Brucella bacteria in a clinical specimen, using an agglutination method. It is commonly used for the detection of infection with or exposure to Brucella bacteria which may include B. abortus and B. melitensis.	62366



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Coagulation Reagents line			
Product Name	Product Code	Intended use	GMDN Code
PT Reagents	CR001	A collection of reagents and other associated materials intended to be used for the quantitative measurement of the prothrombin time (PT) of a clinical specimen, with or without standardization to the international normalized ratio (INR), using a clotting method.	55983
APTT Reagents	CR002	A collection of reagents and other associated materials intended to be used for the quantitative measurement of the activated partial thromboplastin time (APTT) of a clinical specimen.	55981