



# Certificate of CE-Registration

This is to certify that, in accordance with the *In Vitro* Diagnostic Medical Device Directive 98/79/EC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:

**Spectrum for diagnostic industries-Free zone (SDI)  
Cairo Port Said Avenue, Block 5  
Ismailia free zone industrial area  
Ismailia  
EGYPT**

as stipulated and demanded by the aforementioned Directive. The European Databank on Medical Devices (EUDAMED) is established as of May 1, 2011. The German Competent Authority is notified of the manufacturer's *in vitro* diagnostic medical devices and has allocated registration numbers shown in:

**Annex A dated September 12, 2018**

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the *in vitro* diagnostic medical devices fulfill the applicable requirements of Directive 98/79/EC. In compliance with German law, a safety officer has been appointed for Germany.

2018-09-12

Ludger Möller  
President  
MDSS GmbH

**Annex A dated September 12, 2018**  
**Manufacturer: Spectrum For Diagnostic Industries - Free Zone**

REF	Device Names (notified)	Optional information	Nomenclature	Code (notified)	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
182 02 125	Alanine aminotransferase (ALT/GPT) - Colorimetric	2 x 125 ml	EDMA	11 01 01 03	Alanine Amino-Transferase	"Other"	NA	DE/CA09/0170/S47/IVD/057
180 04 025	Alanine aminotransferase (ALT/GPT) UV-kinetic (1+1)	4 x 25 ml	EDMA	11 01 01 03	Alanine Amino-Transferase	"Other"	NA	DE/CA09/0170/S47/IVD/057
179 02 020	Alanine aminotransferase (ALT/GPT) UV-kinetic (4+1)	2 x 20 ml	EDMA	11 01 01 03	Alanine Amino-Transferase	"Other"	NA	DE/CA09/0170/S47/IVD/057
179 01 050		1 x 50 ml						
179 10 010		10 x 10 ml						
179 04 050		4 x 50 ml						
159 04 025	Alkaline phosphatase (ALP) Kinetic - IFCC(1 + 1)	4 x 25 ml	EDMA	11 01 01 05	Alkaline Phosphatase - Total	"Other"	NA	DE/CA09/0170/S47/IVD/058-01
158 02 020	Alkaline phosphatase (ALP) Kinetic - IFCC(4 + 1)	2 x 20 ml	EDMA	11 01 01 05	Alkaline Phosphatase - Total	"Other"	NA	DE/CA09/0170/S47/IVD/058-01
158 01 050		1 x 50 ml						
158 10 010		10 x 10 ml						
158 04 050		4 x 50 ml						
161 02 020	$\alpha$ -Amylase (4+1)	2 x 20 ml	EDMA	11 01 01 07	Amylase - Total	"Other"	NA	DE/CA09/0170/S47/IVD/060
161 10 010		10 x 10 ml						
174 04 025	Aspartate aminotransferase (AST/GOT) UV-Kinetic (1+1)	4 x 25 ml	EDMA	11 01 01 10	Aspartate Amino-Transferase	"Other"	NA	DE/CA09/0170/S47/IVD/056
173 02 020	Aspartate aminotransferase (AST/GOT) UV-Kinetic (4+1)	2 x 20 ml	EDMA	11 01 01 10	Aspartate Amino-Transferase	"Other"	NA	DE/CA09/0170/S47/IVD/056
173 01 050		1 x 50 ml						
173 10 010		10 x 10 ml						
173 04 050		4 x 50 ml						
176 02 125	Aspartate aminotransferase (AST/GOT)-Colorimetric	2 x 125 ml	EDMA	11 01 01 10	Aspartate Amino-Transferase	"Other"	NA	DE/CA09/0170/S47/IVD/056
101 02 125	Albumin - BCG	2 x 125 ml	EDMA	11 02 01 01	Albumin (CC)	"Other"	NA	DE/CA09/0170/S47/IVD/055
101 05 125		5 x 125 ml						
101 04 250		4 x 250 ml						

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191 01 050 191 02 030 191 05 030	Ammonia (UV-Single Reagent)	1 x 50 ml 2 x 30 ml 5 x 30 ml	EDMA	11 03 01 01	Ammonia	"Other"	NA	DE/CA09/0170/S47/IVD/054-01
447 01 005 447 05 005	Abnormal control	1 x 5 ml 5 x 5 ml	EDMA	11 50 01 01	Assayed Multicomponent Controls (CC)	"Other"	NA	DE/CA09/0170/S47/IVD/053
376 02 020	Antistreptolysin O (ASO) Turbi Latex	-	EDMA	12 11 01 05	Anti-Streptolysin O Reaction Time / Titre (quantitative)	"Other"	NA	DE/CA09/0170/S47/IVD/051-01
391 02 020	Antistreptolysin O (ASO) Immuno-Turbidimetry	-	EDMA	12 11 01 05	Anti-Streptolysin O (quantitative)	"Other"	NA	DE/CA09/0170/S47/IVD/052-01
366 03 045 366 03 025 366 02 045 366 02 025 366 01 005	Antistreptolysin O Titre (ASOT)	1 x 4.5 ml 1 x 2.5 ml 1 x 4.5 ml 1 x 2.5 ml 1 x 5 ml	EDMA	12 11 01 04	Anti-Streptolysin O Reaction Time / Titre (qualitative)	"Other"	NA	DE/CA09/0170/S47/IVD/052-01
424 06 004	APTT Reagent	6 x 4 ml	EDMA	13 02 01 02	Activated Partial Thromboplastin Time	"Other"	NA	DE/CA09/0170/S47/IVD/050
108 02 090	Bilirubin Total and direct DMSO, Colorimetric	2 x 90 ml	EDMA	11 02 01 03	Bilirubin	"Other"	NA	DE/CA09/0170/S47/IVD/049-01
104 05 125	Bilirubin Jendrassik Grof	500 ml	EDMA	11 02 01 03	Bilirubin	"Other"	NA	DE/CA09/0170/S47/IVD/049-01
107 02 030 107 05 030	Total Bilirubin	2 x 30 ml 30 ml	EDMA	11 02 01 03	Bilirubin	"Other"	NA	DE/CA09/0170/S47/IVD/049-01
106 02 125	Pediatric Total Bilirubin	2 x 125 ml	EDMA	11 02 01 03	Bilirubin	"Other"	NA	DE/CA09/0170/S47/IVD/049-01
353 01 005	Brucella Melitensis	1x 5 ml	EDMA	15 01 90 01	Brucella	"Other"	NA	DE/CA09/0170/S47/IVD/048
351 01 005	Brucella Abortus	1x 5 ml	EDMA	15 01 90 01	Brucella	"Other"	NA	DE/CA09/0170/S47/IVD/048
355 02 025 355 02 005	Brucella Combo	2 x 2.5 ml 5 ml	EDMA	15 01 90 01	Brucella	"Other"	NA	DE/CA09/0170/S47/IVD/048
359 01 005	Brucella Rose Bengal	1x 5 ml	EDMA	15 01 90 01	Brucella	"Other"	NA	DE/CA09/0170/S47/IVD/048

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368 03 045	C Reactive Protein (CRP)	1 x 4.5 ml	EDMA	12 11 01 09	C-Reactive Protein	"Other"	NA	DE/CA09/0170/S47/IVD/047-01
368 03 025	Rapid latex slide test	2.5 ml						
368 02 045		4.5 ml						
368 02 025		1 x 2.5 ml						
368 01 005		5 ml						
378 02 020	C REACTIVE PROTEIN (CRP) Turbi Latex	-	EDMA	12 11 01 09	C-Reactive Protein	"Other"	NA	DE/CA09/0170/S47/IVD/047-01
393 02 020	C REACTIVE PROTEIN (CRP) Immuno-Turbidimetry	-	EDMA	12 11 01 09	C-Reactive Protein	"Other"	NA	DE/CA09/0170/S47/IVD/047-01
197 01 050	Calcium Arsenazo III	50 ml	EDMA	11 03 01 03	Calcium	"Other"	NA	DE/CA09/0170/S47/IVD/046
197 02 030		2 ml						
197 05 030		5 x 30 ml						
194 02 030	Calcium O-CPC	2 x 30 ml	EDMA	11 03 01 03	Calcium	"Other"	NA	DE/CA09/0170/S47/IVD/046
194 02 125		2 x 125 ml						
448 01 003	Calibrator For Clinical Chemistry	1 x 3 ml	EDMA	11 50 03 01	Calibrators Multicomponent (CC)	"Other"	NA	DE/CA09/0170/S47/IVD/045
448 05 003		5 x 3 ml						
384 01 012	Cardiac Troponin I Assay (cTnI)	-	EDMA	12 13 01 07	Troponin I/T	"Other"	NA	DE/CA09/0170/S47/IVD/044-01
401 01 020	Ceruloplasmin Immuno-Turbidimetry	-	EDMA	12 01 03 02	Ceruloplasmin	"Other"	NA	DE/CA09/0170/S47/IVD/043
200 01 050	Chloride	1 x 50 ml	EDMA	11 03 01 04	Chloride	"Other"	NA	DE/CA09/0170/S47/IVD/042-01
200 02 030	(Colorimetric method)	2 x 30 ml						
200 05 030		5 x 30 ml						
110 01 050	Cholesterol CHOD-PAP	1 x 50 ml	EDMA	11 02 01 05	Cholesterol	"Other"	NA	DE/CA09/0170/S47/IVD/041
110 02 030		2 x 30 ml						
110 05 030		5 x 30 ml						
520 30 030	CMV IgG/IgM Rapid Test-Cassette	-	EDMA	15 70 90 01	CMV - Rapid Test	"Other"	NA	DE/CA09/0170/S47/IVD/040
203 02 030	Carbon Dioxide (CO2) (Colorimetric PEPC)	2 x 30 ml	EDMA	11 70 31 01	Carbon Dioxide - Electrodes (BG)	"Other"	NA	DE/CA09/0170/S47/IVD/039

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206 01 050 206 02 030 206 05 030	Copper (Colorimetric with Dibrom- PAESA)	1 x 50 ml 2 x 30 ml 5 x 30 ml	EDMA	11 02 01 06	Copper	"Other"	NA	DE/CA09/0170/S47/IVD/038-01
123 02 125 123 04 250	Creatinine. Jaffé	2 x 125 ml 4 x 250 ml	EDMA	11 02 01 07	Creatinine	"Other"	NA	DE/CA09/0170/S47/IVD/037
125 04 125	Creatinine colorimetric	4 x 125 ml	EDMA	11 02 01 07	Creatinine	"Other"	NA	DE/CA09/0170/S47/IVD/037
164 05 005 164 05 010	Creatine Kinase (CK) (4+1)	5 x 5 ml 5 x 10 ml	EDMA	11 01 01 13	Creatine Kinase - Total	"Other"	NA	DE/CA09/0170/S47/IVD/036
167 05 005 167 05 010	CREATINE KINASE MB (CK-MB)- (4+1)	5 x 5 ml 5 x 10 ml	EDMA	11 01 01 14	Creatine Kinase - MB Activity"(CC)	"Other"	NA	DE/CA09/0170/S47/IVD/034
395 01 020	CYSTATIN-C Immunoturbidimetry	-	EDMA	12 01 90 09	Cystatin C	"Other"	NA	DE/CA09/0170/S47/IVD/035
428 01 020	D-Dimer Turbi Latex	-	EDMA	13 02 05 03	D-Dimer	"Other"	NA	DE/CA09/0170/S47/IVD/033
382 02 020	Ferritin Turbi Latex	2 x 20 ml	EDMA	12 07 01 02	Ferritin	"Other"	NA	DE/CA09/0170/S47/IVD/032
426 01 020	FIBRINOGEN Immuno - Turbidimetry	-	EDMA	13 02 02 01	Fibrinogen Assays (Factor I)	"Other"	NA	DE/CA09/0170/S47/IVD/031
184 10 001	Glucose-6-Phosphate dehydrogenase (G-6-PD)	10 x 1 ml	EDMA	13 01 09 01	Cellular enzyme determination reagents (G-6- PDH, Pyuvate Kinase)	"Other"	NA	DE/CA09/0170/S47/IVD/030
128 02 125 128 05 125 128 04 250	Glucose GOD - PAP	2 x 125 ml 5 x 125 ml 4 x 250 ml	EDMA	11 02 01 13	Glucose	"Other"	NA	DE/CA09/0170/S47/IVD/029
526 30 030	H. pylori Ag Rapid Test Cassette (Fecal Specimen)	-	EDMA	15 70 01 02	H. pylori - RT & POC	"Other"	NA	DE/CA09/0170/S47/IVD/028
524 30 030	H. pylori Ab Rapid Test Cassette (Serum, Plasma and Whole Blood)	-	EDMA	15 70 01 02	H. pylori - RT & POC	"Other"	NA	DE/CA09/0170/S47/IVD/028

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403 01 020	HAPTOGLOBIN (HAP) Immuno Turbidimetry	-	EDMA	12 01 03 03	Haptoglobin	"Other"	NA	DE/CA09/0170/S47/IVD/027
134 05 125 134 04 250	Hemoglobin (Ready-To-Use)Drabkin's Solution	5 x 125 ml 4 x 250 ml	EDMA	13 01 70 01	Haemoglobin (Hb)	"Other"	NA	DE/CA09/0170/S47/IVD/026
132 02 10	HbA1c Turbidimetric Immunoassay	-	EDMA	11 02 01 14	Glycosylated/Glycated Haemoglobin (CC)	"Other"	NA	DE/CA09/0170/S47/IVD/025
131 15 003	Glycosylated Hemoglobin (GHb) (Ion Exchange Resin method)	15 x 3 ml	EDMA	11 02 01 14	Glycosylated/Glycated Haemoglobin (CC)	"Other"	NA	DE/CA09/0170/S47/IVD/025
512 25 025	HCG One Step Pregnancy Test Device (Urine/Serum)	-	EDMA	12 70 05 02	HCG - Rapid Test	"Other"	NA	DE/CA09/0170/S47/IVD/024
116 01 040	HDL Cholesterol Direct Enzymatic colorimetric, Liquid	R1 30 ml/R210 ml	EDMA	11 02 01 15	High Density Lipoprotein Cholesterol	"Other"	NA	DE/CA09/0170/S47/IVD/023
113 01 050	HDL Cholesterol Precipitant	1 x 50 ml	EDMA	11 02 01 15	High Density Lipoprotein Cholesterol	"Other"	NA	DE/CA09/0170/S47/IVD/023
209 01 050 209 02 030 209 05 030	Total Iron Chromazurol B	1 x 50 ml 2 x 30 ml 5 x 30 ml	EDMA	11.02.01.16	Iron (CC)	"Other"	NA	DE/CA09/0170/S47/IVD/022
137 05 020	Lactate (4+1) Enzymatic colorimetric (LOX / PAP)	5 x 20 ml	EDMA	11 02 01 18	Lactate	"Other"	NA	DE/CA09/0170/S47/IVD/021-01
119 01 040	LDL CHOLESTEROL Direct Enzymatic colorimetric, Liquid	R1 1 x 30 ml R2 1 x 10 ml	EDMA	11 02 01 21	Low Density Lipoprotein Cholesterol including sd-LDL	"Other"	NA	DE/CA09/0170/S47/IVD/020
188 02 020	Lipase Colorimetric (DGMRE)	-	EDMA	11 01 01 23	Lipase	"Other"	NA	DE/CA09/0170/S47/IVD/019
212 01 050 212 02 030 212 05 030	Magnesium Phosphonazo III	1 x 50 ml 2 x 30 ml 5 x 30 ml	EDMA	11 03 01 07	Magnesium	"Other"	NA	DE/CA09/0170/S47/IVD/018

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399 02 020	MICROALBUMIN (MAU) Immuno Turbidimetry	-	EDMA	12 01 03 01	Albumin (IC) incl. uAlbumin	"Other"	NA	DE/CA09/0170/S47/IVD/017
140 02 050	Micro Total Protein (MT-P) Pyrogallol - Red	2 x 50 ml	EDMA	11 02 01 30	Total Protein	"Other"	NA	DE/CA09/0170/S47/IVD/016
143 02 125 143 04 250	Total protein	2 x 125 ml 4 x 250 ml	EDMA	11 02 01 30	Total protein	"Other"	NA	DE/CA09/0170/S47/IVD/016
446 01 005 446 05 005	Normal control	1 x 5 ml 5 x 5 ml	EDMA	11 50 01 01	Assayed Multicomponent Sera (CC)	"Other"	NA	DE/CA09/0170/S47/IVD/015
215 01 050 215 02 030 215 05 030	Phosphorus UV-phosphomolybdate method.	1 x 50 ml 2 x 30 ml 5 x 30 ml	EDMA	11 03 01 08	Phosphate inorganic / Phosphorus	"Other"	NA	DE/CA09/0170/S47/IVD/014
423 02 001	Plasma control set For coagulation Assays	1 ml Path. + 1 ml Norm	EDMA	13 02 50 02	Haemostasis Controls Plasmas	"Other"	NA	DE/CA09/0170/S47/IVD/013
218 01 050 218 02 030 218 05 030	Potassium	1 x 50 ml 2 x 30 ml 5 x 30 ml	EDMA	11 03 01 09	Potassium	"Other"	NA	DE/CA09/0170/S47/IVD/012
422 06 004 422 08 006	PT Reagent ISI 1.05	6 x 4 ml 8 x 6 ml	EDMA	13 02 01 01	Prothrombin time ( Quick Test )	"Other"	NA	DE/CA09/0170/S47/IVD/011
416 06 004 416 08 006	PT Reagent ISI 1.5	6 x 4 ml 8 x 6 ml	EDMA	13 02 01 01	Prothrombin time ( Quick Test )	"Other"	NA	DE/CA09/0170/S47/IVD/011
380 02 020	RHEUMATOID FACTOR (RF)	-	EDMA	12 11 01 10	Rheumatoid Factors	"Other"	NA	DE/CA09/0170/S47/IVD/010-01
397 02 020	RHEUMATOID FACTOR (RF) ImmunoTurbidimetry 3rd Generation	-	EDMA	12 11 01 10	Rheumatoid Factors	"Other"	NA	DE/CA09/0170/S47/IVD/010-01
370 03 045 370 03 025 370 02 045 370 02 025 370 01 005	Rheumatoid Factor (RF) Rapid latex slide test	1 x 4.5 ml 1 x 2.5 ml 1 x 4.5 ml 1x 2.5 ml 1 x 5 ml	EDMA	12 11 01 10	Rheumatoid Factors	"Other"	NA	DE/CA09/0170/S47/IVD/010-01

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358 03 002	RPR Syphilis Test	-	EDMA	15 01 03 01	Syphilis Antigen Detection	"Other"	NA	DE/CA09/0170/S47/IVD/009
221 01 050 221 02 030 221 05 030	Sodium	1 x 50 ml 2 x 30 ml 5 x 30 ml	EDMA	11 03 01 10	Sodium	"Other"	NA	DE/CA09/0170/S47/IVD/008
210 02 050	Direct Serum Total Iron Binding Capacity (TIBC)	-	EDMA	11 02 01 17	Iron Binding Capacity - Total (CC)	"Other"	NA	DE/CA09/0170/S47/IVD/007
146 01 050 146 02 030 146 05 030	Triglycerides	1 x 50 ml 2 x 30 ml 5 x 30 ml	EDMA	11 02 01 31	Triglycerides	"Other"	NA	DE/CA09/0170/S47/IVD/006
521 25 025	"S.typhi-S.paratyphi "A Direct Antigen Detection	-	EDMA	15 01 10 03	Salmonella Antibody Assays	"Other"	NA	DE/CA09/0170/S47/IVD/005-01
522 30 030	Typhoid IgG/IgM Rapid Test-Cassette	-	EDMA	15 01 10 03	Salmonella Antibody Assays	"Other"	NA	DE/CA09/0170/S47/IVD/005-01
356 04 005 356 08 005	Widal Test (Salmonella Ab)	4 x 5 ml 8 x 5 ml	EDMA	15 01 10 03	Salmonella Antibody Assays	"Other"	NA	DE/CA09/0170/S47/IVD/005-01
152 05 030	Urea/BUN . (UV) (4+1)	5 x 30 ml	EDMA	11 02 01 04	Urea/Blood Urea Nitrogen	"Other"	NA	DE/CA09/0170/S47/IVD/004
149 01 125 149 04 125	Urea/BUN - Colorimetric	1 x 125 ml 4 x 125 ml	EDMA	11 02 01 04	Urea/Blood Urea Nitrogen	"Other"	NA	DE/CA09/0170/S47/IVD/004
155 01 050 155 02 030 155 05 030	Uric acid Uricase-POD	1 x 50 ml 2 x 30 ml 5 x 30 ml	EDMA	11.02.01.32	Uric Acid	"Other"	NA	DE/CA09/0170/S47/IVD/003
528 01 100	URINE STRIPS	-	EDMA	11 70 02 02	Urine Multi-constituent Test Strips (manual)	"Other"	NA	DE/CA09/0170/S47/IVD/002-01
530 01 100	URINE STRIPS (Reagent strips for urinalysis for ten parameters)	-	EDMA	11 70 02 02	Urine Multi-constituent Test Strips (manual)	"Other"	NA	DE/CA09/0170/S47/IVD/002-01



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171 04 025	γ - Glutamyl transferase (γGT) (1+1)	4 x 25 ml	EDMA	11 01 01 16	Gamma Glutamyltransferase	"Other"	NA	DE/CA09/0170/S47/IVD/059
170 02 020 170 01 050 170 10 010 170 04 050	γ - Glutamyl transferase (γGT) (4+1)	2 x 20 ml 1 x 50 ml 10 x 10 ml 4 x 50 ml	EDMA	11 01 01 16	Gamma Glutamyltransferase	"Other"	NA	DE/CA09/0170/S47/IVD/059
225 01 050 225 02 030 225 05 030	Zinc (Colorimetric Method with 5-Brom-PAPS)	1 x 50 ml 2 x 30 ml 5 x 30 ml	EDMA	11 02 01 33	Zinc	"Other"	NA	DE/CA09/0170/S47/IVD/001-01
516 30 030	Cardiac Troponin I Rapid Test Cassette (serum/plasma/whole blood)	-	EDMA	12 70 13 03	Troponin I/T - Rapid Test	"Other"	NA	DE/CA09/0170/S47/IVD/062
186 04 025	Lactate dehydrogenase (LDH)UV-kinetic (1+1)	4 x 25 ml	EDMA	11 01 01 20	Lactate Dehydrogenase P ( LDH - P --> L )	"Other"	NA	DE/CA09/0170/S47/IVD/061
185 02 020 185 01 050 185 10 010 185 04 050	Lactate dehydrogenase(LDH) UV-Kinetic (4+1)	2 x 20 ml 1 x 50 ml 10 x 10 ml 4 x 50 ml	EDMA	11 01 01 20	Lactate Dehydrogenase P ( LDH - P --> L )	"Other"	NA	DE/CA09/0170/S47/IVD/061