

Certificate of CE-Registration



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

Arena BioScien
Block 5, Street 9 inside the Ismailia Free Zone
41511 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 December 14, 2023

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.

2023-12-14

Dr. Philipp Hohenbrink
Director of International Operations
MDSS GmbH

Annex A dated December 14, 2023
Arena BioScien

REF	Device Names (notified)	Nomenclature	Code (notified)	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
BS.1/AL02.100.0200 BS.1/AL02.125.0250 BS.1/AL01.250.0250 BS.1/AL01.500.0500	Albumin	EDMA	11.02.01.01	Albumin (CC)	Other IVD	N/A	DE/CA09/00090385
BS.1/AP05.010.0050 BS.1/AP05.020.0100 BS.1/AP02.025.0050 BS.1/AP02.050.0100	Alkaline Phosphatase (9+1)	EDMA	11.01.01.05	Alkaline Phosphatase - Total	Other IVD	N/A	DE/CA09/00090386
BS.1/AM05.010.0050 BS.1/AM05.020.0100 BS.1/AM02.025.0050 BS.1/AM02.050.0100	Amylase - Total	EDMA	11.01.01.07	Amylase Total	Other IVD	N/A	DE/CA09/00090387
BS.1/BL01.050.0050 BS.1/BL02.050.0100 BS.1/BL05.050.0250	Bilirubin (Total + Direct)	EDMA	11.02.01.03	Bilirubin	Other IVD	N/A	DE/CA09/00090388
BS.1/BD01.050.0050 BS.1/BD02.050.0100 BS.1/BD05.050.0250	Bilirubin (Total + Direct)	EDMA	11.02.01.03	Bilirubin	Other IVD	N/A	DE/CA09/00090388
BS.1/CA02.025.0050 BS.1/CA04.025.0100 BS.1/CA02.050.0100 BS.1/CA02.100.0200	Calcium	EDMA	11.03.01.03	Calcium	Other IVD	N/A	DE/CA09/00090389
BS.1/CA02.025.0050 BS.1/CA04.025.0100 BS.1/CA02.050.0100 BS.1/CA02.100.0200	Calcium	EDMA	11.03.01.03	Calcium	Other IVD	N/A	DE/CA09/00090389
BS.1/CL02.025.0050 BS.1/CL04.025.0100 BS.1/CL02.050.0100 BS.1/CL02.100.0200	Chloride	EDMA	11.03.01.04	Chloride	Other IVD	N/A	DE/CA09/00090390
BS.1/CH02.025.0050 BS.1/CH04.025.0100 BS.1/CH02.050.0100 BS.1/CH02.100.0200	Cholesterol	EDMA	11.02.01.05	Cholesterol	Other IVD	N/A	DE/CA09/00090391
BS.1/MB05.005.0025 BS.1/MB05.010.0050	CK-MB	EDMA	11.01.01.14	Creatine Kinase - MB Activity" (CC)	Other IVD	N/A	DE/CA09/00090392
BS.1/CK05.005.0025 BS.1/CK05.010.0050	CK-Nac	EDMA	11.01.01.13	Creatine Kinase - Total	Other IVD	N/A	DE/CA09/00090393
BS.1/CR02.050.0100 BS.1/CR02.100.0200 BS.1/CR02.125.0250 BS.1/CR02.250.0500	Creatinine	EDMA	11.02.01.07	Creatinine	Other IVD	N/A	DE/CA09/00090394

YAB



Annex A dated December 14, 2023
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BS.1/CC02.050.0100 BS.1/CC02.100.0200 BS.1/CC02.125.0250 BS.1/CC02.250.0500	Creatinine	EDMA	11.02.01.07	Creatinine	Other IVD	N/A	DE/CA09/00090394
BS.1/HB02.020.0040 BS.1/HB02.040.0080 BS.1/HB02.050.0100	Haemoglobin Conc.	EDMA	13.01.02.01	Haemoglobin determinations (Total Hb)	Other IVD	N/A	DE/CA09/00090395
BS.1/HB01.250.0250 BS.1/HB04.250.1000 BS.1/HB01.500.0500	Haemoglobin Ready	EDMA	13.01.02.01	Haemoglobin determinations (Total Hb)	Other IVD	N/A	DE/CA09/00090395
BS.1/HCO1.050.0050 BS.1/HCO1.100.0100	HDL Cholesterol	EDMA	11.02.01.15	High Density Lipoprotein Cholesterol	Other IVD	N/A	DE/CA09/00090398
BS.1/HDO1.020.0040 BS.1/HDO2.020.0040	HDL	EDMA	11.02.01.15	High Density Lipoprotein Cholesterol	Other IVD	N/A	DE/CA09/00090398
BS.1/LC05.005.0025 BS.1/LC10.005.0100	LDL Cholesterol	EDMA	11.02.01.21	Low Density Lipoprotein Cholesterol including sd-LDL	Other IVD	N/A	DE/CA09/00090399
BS.1/GL01.100.0100 BS.1/GL02.125.0250 BS.1/GL01.250.0250 BS.1/GL02.100.0200 BS.1/GL04.125.0500 BS.1/GL02.250.0500	Glucose	EDMA	11.02.01.13	Glucose	Other IVD	N/A	DE/CA09/00090400
BS.1/GT06.005.0030 BS.1/GT06.010.0060	γ -Glutamyltransferase (GGT) (9+1)	EDMA	11.01.01.16	Gamma Glutamyltransferase	Other IVD	N/A	DE/CA09/00090401
BS.1/OT05.010.0050 BS.1/OT10.010.0100 BS.1/OT05.020.0100 BS.1/OT02.025.0050 BS.1/OT04.025.0100 BS.1/OT04.050.0200	Aspartate Aminotransferase (AST/GOT)	EDMA	11.01.01.10	Aspartate Amino-Transferase	Other IVD	N/A	DE/CA09/00090402
BS.1/OT02.050.0100 BS.1/OT02.100.0200 BS.1/OT02.125.0250	Aspartate Aminotransferase (AST/GOT)	EDMA	11.01.01.10	Aspartate Amino-Transferase	Other IVD	N/A	DE/CA09/00090402
BS.1/PT05.010.0050 BS.1/PT10.010.0100 BS.1/PT05.020.0100 BS.1/PT02.025.0050 BS.1/PT04.025.0100 BS.1/PT04.050.0200	Alanine Aminotransferase (ALT/GPT)	EDMA	11.01.01.03	Alanine Amino-Transferase	Other IVD	N/A	DE/CA09/00090403



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BS.1/PT02.050.0100 BS.1/PT02.100.0200 BS.1/PT02.125.0250	Alanine Aminotransferase (ALT/GPT)	EDMA	11.01.01.03	Alanine Amino-Transferase	Other IVD	N/A	DE/CA09/00090403
BS.1/LD05.005.0025 BS.1/LD10.005.0050 BS.1/LD05.010.0050 BS.1/LD02.025.0050 BS.1/LD04.025.0100	LDH	EDMA	11.01.01.19	Lactate Dehydrogenase P(LDH -P --> L)	Other IVD	N/A	DE/CA09/00090404
BS.1/LAC02.020.0040 BS.1/LAC02.025.0050 BS.1/LAC02.050.0100	Lactate	EDMA	11.02.02.18	Lactate	Other IVD	N/A	DE/CA09/00090405
BS.1/LIP02.020.0040 BS.1/LIP02.025.0050 BS.1/LIP02.050.0100	Lipase	EDMA	11.01.01.23	Lipase	Other IVD	N/A	DE/CA09/00090406
BS.1/MG02.025.0050 BS.1/MG04.025.0100 BS.1/MG02.050.0100 BS.1/MG02.100.0200	Magnesium	EDMA	11.03.01.07	Magnesium	Other IVD	N/A	DE/CA09/00090407
BS.1/PH02.025.0050 BS.1/PH04.025.0100 BS.1/PH02.050.0100 BS.1/PH02.100.0200	Phosphorus	EDMA	11.03.01.08	Phosphate inorganic / Phosphorus	Other IVD	N/A	DE/CA09/00090408
BS.1/PO02.025.0050 BS.1/PO04.025.0100 BS.1/PO02.050.0100 BS.1/PO02.100.0200	Potassium	EDMA	11.03.01.09	Potassium	Other IVD	N/A	DE/CA09/00090414
BS.1/NA02.025.0050 BS.1/NA04.025.0100 BS.1/NA02.050.0100 BS.1/NA02.100.0200	Sodium	EDMA	11.03.01.10	Sodium	Other IVD	N/A	DE/CA09/00090409
BS.1/TP02.125.0250 BS.1/TP01.250.0250 BS.1/TP04.250.1000 BS.1/TP01.500.0500	Total Protein	EDMA	11.02.01.30	Total Protein	Other IVD	N/A	DE/CA09/00090410
BS.1/TI02.025.0050 BS.1/TI04.025.0100 BS.1/TI02.050.0100	Total Iron	EDMA	11.02.01.16	Iron (CC)	Other IVD	N/A	DE/CA09/00090411
BS.1/TC02.025.0050 BS.1/TC04.025.0100 BS.1/TC02.050.0100	Total Iron Binding Capacity (TIBC)	EDMA	11.02.01.17	Iron Binding Capacity - Total (CC)	Other IVD	N/A	DE/CA09/00090413

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BS.1/TG02.025.0050 BS.1/TG04.025.0100 BS.1/TG02.050.0100 BS.1/TG02.100.0200	Triglycerides	EDMA	11.02.01.31	Triglycerides	Other IVD	N/A	DE/CA09/00090415
BS.1/UR02.050.0100 BS.1/UR02.100.0200 BS.1/UR02.125.0250	Urea/BUN	EDMA	11.02.01.04	Urea/Blood Urea Nitrogen	Other IVD	N/A	DE/CA09/00090416
BS.1/UU02.050.0100 BS.1/UU02.100.0200 BS.1/UU02.125.0250	Urea/BUN	EDMA	11.02.01.04	Urea/Blood Urea Nitrogen	Other IVD	N/A	DE/CA09/00090416
BS.1/UA02.025.0050 BS.1/UA04.025.0100 BS.1/UA02.050.0100 BS.1/UA02.100.0200	Uric acid	EDMA	11.02.01.32	Uric Acid	Other IVD	N/A	DE/CA09/00090417
BS.1/PT01.005.0005 BS.1/PT01.008.0008 BS.1/PT05.008.0040 BS.1/PT06.008.0048	Thromboplastin (PT) ISI=1.5	EDMA	13.02.01.01	Prothrombin time (Quick Test)	Other IVD	N/A	DE/CA09/00090418
BS.1/PT05.005.0025	Thromboplastin- S (PT) ISI=1.05	EDMA	13.02.01.01	Prothrombin time (Quick Test)	Other IVD	N/A	DE/CA09/00090418
BS.1/PTT01.003.0003 BS.1/PTT05.003.0015 BS.1/PTT06.003.0018 BS.1/PTT01.004.0004 BS.1/PTT05.004.0020	Thrombocelin (APTT)+Calcium Chloride	EDMA	13.02.01.02	Activated Partial Thromboplastin Time	Other IVD	N/A	DE/CA09/00090419
BS.1/FB01.015.0015 BS.1/FB01.020.0020 BS.1/FB01.050.0050	Fibrinogen	EDMA	13.02.02.01	Fibrinogen Assays (Factor I)	Other IVD	N/A	DE/CA09/00090421
BS.1/FD01.015.0015 BS.1/FD01.020.0020 BS.1/FD01.050.0050	FDP	EDMA	13.02.05.02	Fibrinigen Degradation Product	Other IVD	N/A	DE/CA09/00090420
BS.1/DD01.025.0025 BS.1/DD01.050.0050 BS.1/DD01.100.0100	D-Dimer Latex	EDMA	13.02.05.03	D-Dimer	Other IVD	N/A	DE/CA09/00105340
BS.1/PLA01.001.0001	Plasmatrol I	EDMA	13.02.70.50	Haemostasis Controls - RT & POC	Other IVD	N/A	DE/CA09/00090422



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BS.1/PLB01.001.0001	Plasmatrol II	EDMA	13.02.70.50	Haemostasis Controls - RT & PQC	Other IVD	N/A	DE/CA09/00090422
BS.1/PLC01.001.0001	Plasmatrol III	EDMA	13.02.70.50	Haemostasis Controls - RT & PQC	Other IVD	N/A	DE/CA09/00090422
BS.1/ASC1.050.0050 BS.1/ASC1.100.0100	ASOT Latex with controls	EDMA	12.11.01.05	Anti-Streptolysin O (quantitative)	Other IVD	N/A	DE/CA09/00090423
BS.1/ASO1.050.0050 BS.1/ASO1.100.0100	ASOT Latex only	EDMA	12.11.01.05	Anti-Streptolysin O (quantitative)	Other IVD	N/A	DE/CA09/00090423
BS.1/AST1.050.0050 BS.1/AST1.100.0100	Antistreptolysin O (ASO) Turbi Latex	EDMA	12.11.01.05	Anti-Streptolysin O (quantitative)	Other IVD	N/A	DE/CA09/00090423
BS.1/CRC1.050.0050 BS.1/CRC1.100.0100	CRP Latex with controls	EDMA	12.11.01.09	C-Reactive Protein	Other IVD	N/A	DE/CA09/00090424
BS.1/CR01.050.0050 BS.1/CR01.100.0100	CRP Latex only	EDMA	12.11.01.09	C-Reactive Protein	Other IVD	N/A	DE/CA09/00090424
BS.1/CRT1.050.0050 BS.1/CRT1.100.0100	C-Reactive Protein (CRP) Turbi Latex	EDMA	12.11.01.09	C-Reactive Protein	Other IVD	N/A	DE/CA09/00090424
BS.1/RFC1.050.0050 BS.1/RFC1.100.0100	RF Latex with controls	EDMA	12.11.01.10	Rheumatoid Factors	Other IVD	N/A	DE/CA09/00090425
BS.1/RF01.050.0050 BS.1/RF01.100.0100	RF Latex with only	EDMA	12.11.01.10	Rheumatoid Factors	Other IVD	N/A	DE/CA09/00090425
BS.1/RFR1.050.0050 BS.1/RFR1.100.0100	RoseWaller	EDMA	12.11.01.10	Rheumatoid Factors	Other IVD	N/A	DE/CA09/00090425
BS.1/RFT1.050.0050 BS.1/RFT1.100.0100	Rheumatoid Factor (RF) Turbi Latex	EDMA	12.11.01.10	Rheumatoid Factors	Other IVD	N/A	DE/CA09/00090425
BS.1/PRP1.050.0050 BS.1/PRP1.100.0100	RPR Latex Test	EDMA	15.01.03.01	Syphilis Antigen Detection	Other IVD	N/A	DE/CA09/00090507
BS.1/BRA1.100.0100	Brucella A	EDMA	15.01.90.01	Brucella	Other IVD	N/A	DE/CA09/00090427
BS.1/BRM1.100.0100	Brucella M	EDMA	15.01.90.01	Brucella	Other IVD	N/A	DE/CA09/00090427
BS.1/BRB1.100.0100	Brucella Rose Bengal	EDMA	15.01.90.01	Brucella	Other IVD	N/A	DE/CA09/00090427
BS.1/LP01.050.0050 BS.1/LP01.100.0100	SLE Latex	EDMA	13.02.06.07	Lupus Anticoagulant	Other IVD	N/A	DE/CA09/00090428
BS.1/WDC04.005.0100 BS.1/WDC06.005.0150 BS.1/WDC08.005.0200	WIDAL with Control	EDMA	15.01.10.03	Salmonella Antibody Assays	Other IVD	N/A	DE/CA09/00090429
BS.1/WDC01.100.0100	WIDAL typhi (O&H) with control	EDMA	15.01.10.03	Salmonella Antibody Assays	Other IVD	N/A	DE/CA09/00090429
BS.1/WDH01.100.0100	WIDAL typhi (O&H)	EDMA	15.01.10.03	Salmonella Antibody Assays	Other IVD	N/A	DE/CA09/00090429
16 WIDAL Single	WIDAL Single	EDMA	15.01.10.03	Salmonella Antibody Assays	Other IVD	N/A	DE/CA09/00090429



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BS.1/GL01.010.0010 BS.1/ GL01.025.0025 BS.1/ GL01.050.0050	Glycosylated Hemoglobin HBA1C	EDMA	11.02.01.14	Glycosylated/Glycated Haemoglobin (CC)	Other IVD	N/A	DE/CA09/00090430
BS.1/ZN02.025.0050 BS.1/ZN02.050.0100	Zinc	EDMA	11.02.01.33	Zinc	Other IVD	N/A	DE/CA09/00105341
BS.1/GP01.005.0005 BS.1/GP02.005.0010 BS.1/GP05.005.0025	G6PDH	EDMA	13.01.90.01	Cellular enzyme determination reagents (G-6-PDH, Pyruvate Kinase)	Other IVD	N/A	DE/CA09/00090431
BS.1/FER1.050.0050 BS.1/FER1.100.0100 BS.1/FET1.050.0050 BS.1/FET1.100.0100	FERRITIN Turbi Latex	EDMA	12.07.01.02	Ferritin	Other IVD	N/A	DE/CA09/00090432
BS.1/VDO1.050.0050 BS.1/VDO1.100.0100	Vitamin D	EDMA	12.07.02.90	Other Vitamin Tests	Other IVD	N/A	DE/CA09/00105342
BS.1/DIM1.015.0015 BS.1/DIM1.020.0020 BS.1/DIM1.050.0050 BS.1/DIM1.100.0100	D-Dimer Turbid Latex	EDMA	13.02.70.03	D-Dimer - RT & POC	Other IVD	N/A	DE/CA09/00090436
BS.1/HBT1.050.0050 BS.1/HBT1.100.0100	Hemoglobin A1c (HbA1c) Immuno - Turbidimetry	EDMA	12.06.01.06	Glycosylated/Glycated Haemoglobin (IC)	Other IVD	N/A	DE/CA09/00090438
BS.1/CCT1.50.0050 BS.1/CCT1.100.0100	C3 Turbi	EDMA	12.01.02.03	Complement Component C3/C3c	Other IVD	N/A	DE/CA09/00090439
BS.1/CTT1.050.0050 BS.1/CTT1.100.0100	C4 Turbi	EDMA	12.01.02.05	Complement Component C4	Other IVD	N/A	DE/CA09/00090440

