

Anexa nr. 1
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 22 din 30.10.2023

Solicitantul „GBG-MLD” SRL, cu sediul în mun. Chișinău, str. Albisoara 64/2, tel./fax: 022 54 73 73, e-mail office@gbg.md, solicit respectuos înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale ale producătorului **Egyptian Company for Biotechnology – Spectrum Diagnostics** pentru introducerea și punerea la dispoziție pe piață a următoarelor produse, Conform Anexei Nr. 1.1.

Se anexează următoarele acte:

Notificarea pentru înregistrarea dispozitivelor medicale;

Declarația pe proprie răspundere;

Declarația de conformitate;

Scrisoarea de Autorizare;

Data 30.10.2023

Semnătură



Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către
solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	Accept
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	Nr. 8051 din 13.11.2023
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	Glavatchi Dioniță
Semnătura persoanei responsabile	GD S

REF	Device Names (notified)	ANEXA 1.1
262 001	Alanine aminotransferase (ALT/GPT)- Uquizyme (9+1)	
262 002		
262 003		
262 004		
262 005		
262 006	Alanine aminotransferase(ALT/GPT) - Liquizyme (1+1)	
263 001		
263 002		
263 003	Alanine aminotransferase(ALT/GPT) Colorimetric	
264 001		
264 002	Alanine aminotransferase(ALT/GPT) - single reagent	
265 001		
265 002		
265 003		
ZL-265 001		
D-605 001		
D-605 002		
D-605 003		
292 000	Alanine aminotransferase(ALT/GPT)- Liquizyme (4+1)	
292 001		
292 002		
292 003		
292 004		
292 005		
292 006		
292 007		
292 008		
D-604 001	Alanine Aminotransferase (ALT/GPT)-(4+1) UV Kinetic Method	
D-604 002		
D-604 003		
D-604 004		



D-604 005	
215001	Alkaline Phosphatase (ALP) - Liquizyme {1+1} IFCC
215 002	
214 001	Alkaline Phosphatase (ALP) - Liquizyme (9+1) IFCC
214 002	
214 003	
214 004	
214 005,	
ZL-214 001	
216 001	Alkaline Phosphatase (ALP) - Colorimetric
217 001	Alkaline Phosphatase (ALP)-Liquizyme (single reagent)
217 002	
217 003	
D-602 001	Alkaline Phosphatase (4+1) (Kinetic IFCC Method)
D-602 002	
D-602 004	
D-602 005	
D-652 001	Alkaline phosphatase (9 + 1) (Kinetic IFCC Method)
D-652 002	
D-603 001	Alkaline Phosphatase (SingleReagent) (Kinetic IFCC Method)
D-603 002	
D-603 003	
D-603 004	
219 001	Amylase - single reagent
219 002	
ZL-219 001	Amylase (4+1)
D-606 001	Alpha Amylase (4+1) GALG2-CNP
D-606 002	



258 001	Aspartate aminotransferase (AST/GOT)- Liquizyme (9+1)
258 002	
258 003	
258 004	
258 005	
258 006	Aspartate aminotransferase (AST/GOT)- Liquizyme (1+1)
259 001	
259 002	
259 003	
260001	Aspartate aminotransferase (AST) Colorimetric
260002	
261001	Aspartate aminotransferase (AST/GOT)- single reagent
262 002	
261003	
261004	
261005	
261006	
261007	Aspartate aminotransferase (AST/GOT)- Uquizyme (4+1)
ZL-261001	
291000	
291001	
291002	
291003	
291004	
291005	
291 006	
291007	
291008	



D-607 001	Aspartate aminotransferase (AST/GOT) (4+1) UV Kinetic Method
D-607 002	
D-607 003	
D-607 004	
D-608 001	Aspartate aminotransferase (AST/GOT) (Single Reagent)
D-608 002	
D-608 003	
418 001	Cholinesterase DGKC
418 002	
D-662 001	
D-662 002	Creatine Kinase (CK)
238 001	
238 002,	
238 004	
D-614 001	
D-614 002	Creatine Kinase - CK (4+1)
ZL-238 001	
239 001	Creatine Kinase MB
239 002	
239 003	
239 004	
ZL-239 001	Creatine Kinase MB - CK- MB(4+1)
D-615 001	Creatine Kinase MB (CK-MB)
D-615 002	
246 001	γ - Glutamyltransferase(GGT) - Liquizyme (9+1)
246 002	
246 003	
246 004	
246 005	
ZL-246 001	



247 001	γ - Glutamyltransferase (GGT) - Liquizyme (1+1)
247 002	
D-621001 D-621002 D-621003	i.- Glutamyl transferase (GGT) (4+1)
D-622 001	i.- Glutamyltransferase- (GGT)(9+1)
D-629 002	Lactate dehydrogenase (LDH 4+1) -
278 001	Lactate dehydrogenase (LDH) - Liquizyme (9+1)
278 002	
278 003	
278 004	
278 005	
279 001	Lactate dehydrogenase (LDH)- Liquizyme (1+1)
279 002	
283 001	Lactate dehydrogenase (LDH) - liquizyme (4+1)
283 002	
283 003	
283 004	
283 005,	
ZL-283 001	
283 001	Lactate dehydrogenase (LDH) (Single Reagent)
283 002	
283 003	
281 001	Lipase w. Calibrator
ZL-281001	Lipase (4+1)
D-632 001	Lipase Colorimetric (DGMRE)



210 001	Albumin
210 002	
210 003	
210 004	
211001	
211002	Albumin - BCG
211003	
211004	
ZL-211001	
D-601001 D-601002 D-601003	
305 001	Total Bile Acids (TBA)
21-305001	
222 001	Bilirubin (TOTAL AND DIRECT) Jendrassik Grof
222 002	
D-609 001	
D-609 002	
224 001	Bilirubin (Direct)
225 001	Bilirubin Total/Direct DMSO
225 002	
223 001	Bilirubin Total - single reagent
223 002	
ZL--223 001	Bilirubin Plus 5+1
365 001	
365 002	
365 003	
D-658 001	Bilirubin (Total & Direct) DMSO, Colorimetric





321003		
321004		
D-650 001	Urea/BUN - (UV)(9+1)	
230 001	Cholesterol - Uquizyme CHOO-PAP	
230 002		
230 003		
230 004		
230 005		
230 006		
230 007		
230 008,		
230 009		
230 010		
230 011		
ZL-230 001	Cholesterol - Liquizyme CHOO-PAP (Single Reagent)	
0-613 001	Cholesterol CHOO-PAP	
D-613 002		
D-613 003		
D-613 004		
D-613 005		
D-613 006	Copper	
D-613 007		
242 001		
242 002		
232 001		
232 002	Copper - Single reagent	
ZL-232 001		
D-617 001	Copper Colorimetric Test with Dibromo-PAESA	
D-617 002		
0-617 003		
235 001	Creatinine-Colorimetric	
235 002		



D-663 001	Pediatric Total Bilirubin
D-610 001	Total Bilirubin (Single Reagent)
D-610 002	MODIFIED BERGH & MULLER
D-610 003	METHOD
0-610 004	
D-657 001	Bilirubin Direct
319 001	Urea/BUN- Liquizyme (UV)
319 002	
319 003	
319 004	
319 005	
318 001	Urea/BUN - (Modified Urease - Berthlot Method)
318 002	
318 003	
318 004	
320 001	Urea/BUN - single reagent
320 002	
320 003	
320 004	
ZL -320 001	
D-640001	Urea Colorimetric
D-640002	
D-640 003	
D-641001	Urea/BUN - (UV)(4+1)
D-641002	
D-641003	
D-641004	
D-664001	Urea/BUN - LS (Modified Urease- Berthlot Method)
D-664002	
321 001	Urea/BUN - LS (Modified Urease-Berthlot Method)
321002	



235 003		
235 004		
234 001	Creatinine-Jaffe	
234 002		
234 003		
234 004		
234 005 234 006		
237 001	Creatinine-Jaffe - single reagent	
237 002		
237 003		
ZL-237 001		
368 001	Creatinine Plus (5+1)	
368 002		
368 003		
0-619 001	Creatinine - Jaffe	
0-619 002		
0-619 003		
D-618 001	Creatinine - Jaffe (Single Reagent) -	
D-618 002		
250 001		
250 002	Glucose Liquizyme GOD - PAP (Single Reagent)	
250 003		
250 004		
250 005		
250 006		
250 007		
ZL-250 001		



251001	Glucose - HK	Glycosylated Haemoglobin
251 002		
251003		
Glucose GOD-PAP		
D-622 001		
D-622 002		
D-622 003		
D-622 004		
D-622 005		
D-622 006		
Glycosylated Haemoglobin		
254 001		
255 000		
255 001		
255 002		
602 001 ZL-602 001	Glycosylated Haemoglobin (2 Reagents)	HbA1c Plus
401001		
401002		
401003		
401004		
401005		
D-659 001	Glycosylated Hemoglobin (HbA1c) - (Ion Exchange)	Hemoglobin Ale (HbA1c) TwinAle Analyzer
D-659 002		
D-858 001 T		
602 001		
401001-M		
Hemoglobin Ale (HbA1c) TwinAle Analyzer		Hemoglobin Ale (HbA1c) TwinAle Analyzer
HbA1c plus		
Hemoglobin A1c(HbA1c)Turbidimetric Immunoassay		
602 001-1		
602 000-1		





401001 401002	Reagents for STAT LAB T Analyzer - & Auto Chemistry Analyzer HbA1c kit
266 001 266 002	HDL Cholesterol - Precipitant
267 001 267 002	HDLCholesterol - Direct Reagent
ZL-267 001	HDLCholesterol - Direct Reagent(3+1)
623 001 623 002	HDL Cholesterol - Precipitation
D-624 001	HDL Cholesterol Direct Enzymatic - colorimetric, liquid
D-628 001 D-628 002 D-628 003 D-628 004	Total Iron Chromazurol B Single Reagent
270 001	Total Iron and Total Iron BindingCapacity Reagent set Iron-NP Single reagent
271001 271002	
ZL-271001	
269 001 269 002	Total Iron chromazurol B {SingleReagent}
D-653 001	Direct Serum Total Iron BindingCapacity (TIBC)
274 001 274 002	Lactate - Liquizyme
ZL-274 001 D-648 001	Lactate - (9+1)



280 001	LDL-Cholesterol Direct Reagent
280 002	
ZL-280 001	LDL-Cholesterol Direct Reagent (3+1)
D-631 001	LDL Cholesterol Direct Enzymatic colorimetric, Liquid
290 001	Oxalic acid
282 001	Micrototal Protein (MT-P)
282 002	
282 003	
ZI-282 001	
310 001	Total Protein (Single Reagent)
310 002	
310 003	
310 004	
310 005,	
ZI-310 001	
D-634 001	Micrototal Protein (MT-P) Pyrogallol - Red
D-634 002	
D-634003	
D-634004	
D-638 001	Total protein (Biuret Reagent)
D-638 002	
D-638 003	
314 001	Triglycerides (Single Reagent)
314 002	
314 003	
314 004	
314 005	
314 006	
314 007	
314 008	
314 009	
314 010	



314 011, ZL-314 001		
D-639 001	Triglycerides GPO-PAP	
D-639 002		
D-639 003		
D-639 004		
D-639 005		
D-639 006		
322 001	Uric acid - Liquizyme (9+1) Uricase - PAP	
322 002		
322 003		
322 004		
323 001	Uric acid - single reagent	
323 002		
323 003		
323 004		
323 005		
323 006		
ZL-323 001		
D-643 001	Uric acid	
D-643 002		
D-643 003		
D-643 004		
D-643 005		
D-643 006		
D-643 007		
330 001	Zinc - single reagent	
330 002		
ZL-330 001		
D-644001	Zinc Colorimetric Test with 5-Bromo-PAPS	
D-644002		
D-644003		



218 001	Ammonia - Liquizyme (9+1)
220 001	Ammonia - single reagent
220 002	
ZL-220 001	
	Ammonia
0-645 001	
0-645 002	
0-645 003	
226 001	Calcium OCPC
226 002	
226 003	
	Carbon Dioxide (CO2)(Colorimetric PEPC)
0-616 001	
0-616 002	
0-616 003	
228 001228 002	Carbon Dioxide (CO2)(Colorimetric PEPC)
	Calcium Arsenazo III
227 001	
227 002	
227 003	
0-611001	
0-611002	
0-611003	
ZL-227 001	Calcium Arsenazo III (Single Reagent)
0-612 001	Calcium O-CPC
0-612 002	
ZL-233 001	Chloride Single Reagent
0-620001	
0-620002	
285 001	Magnesium - single reagent
285 002	



ZL-285 001		
D-633 001	Magnesium Phosphonazo III	
D-633 002		
D-633 003		
294 001	Phosphorous UV (Single Reagent)	
294 002		
294 003		
ZL-294 001		
0-635 001	Phosphorus - UV Method	
D-635 002		
0-635 003		
298 001	Potassium (Single Reagent)	
298 002		
298 003		
298 004		
ZL-298 001		
D-636 001	Potassium Tetraphenylborate Method without Deproteinization	
D-636 002		
D-636 003		
D-636 004		
302 001	Sodium	
302 002		
303 001	Sodium - single reagent	
303 002		
303 003		
ZL-303 001		
D-637 001		
D-637 002		
D-637 003		
D-637 004		



326 001	SP-Normotrol
326 002	
327 001	SP-Pathotrol
327 002	
	SP-Multical
328 001	
328 002	
1100010	Uritrak - 1,2,3, 5 and 10
1100020	
1100030	
1100050	
1100100	
D-795 001	Urine strips
D-795 002	Urine strips Reagent strips forurinalysis for ten parameters
350 001	Glucose Standard (For Urine)
350 002	
304 001	Sodium Standard Set (For Urine)
375 001	Kappa Light Chain serum Kit (KAP)
378 001	Kappa Light Chain Urine Kit (KAP)
381 001	Lambda Light Chain serum Kit(LAM)
384 001	Lambda Light Chain Urine Kit (LAM)
	Microalbumin (MAU)
600 001	
ZL-600 001	
D-859 001	MICROALBUMIN Immuno Turbiditymetry
592 001	Ceruloplasmin
ZL-592 001	
594 001	Haptoglobin (HAP)
ZL-594 001	



550 001 ZL-550 001	LIPOPROTEIN (a) [Lp(a)]
548 001 ZL-548 001	IMMUNOGLOBULIN E (IgE)
399 001 399 002 399 003 399 004	25-OH Vitamin D
567 001 ZL-567 001	Procalcitonin Assay
562 001 ZL-562 001	FERRITIN
D-562 000 D-562 001	Ferritin Turbi Latex
562 001 562 002 562 001-1 562 002-1	Ferritin Turbi Latex
D-860000 D-860 001	Vitamin D
D-836000 D-836 001 D-836 002	Antistreptolysin O Titre (ASOT)



510 001	Antistreptolysin O Titre (ASOT)
510 002	
510 003	
510 004	
510 005	
510 006	
510 000	Antistreptolysin O Titre (ASOT)
510 001	
510 002	
510 003	
510 004	
510 005	
559 001	Antistreptolysin O Titre - ASOT (2Reagents)
596 001	
ZL- 596-001	
D-851001	
559 001	
559 002	
596 001	Antistreptolysin O (ASO) Immunology - - Turbidimetry
560 001588 001ZL-588 001	
514 000	
514 001	
514 002	
514 003	C Reactive Protein (CRP) (Latex)
514 004	
514 005	



D-837 000	C Reactive Protein (CRP)
D-837 001	
D-837 002	
D-852 001	C Reactive Protein (CRP) Turbi Latex
560 001	C Reactive Protein (CRP) Turbi Latex
560 002	
560 003	
588 001	C Reactive Protein (CRP) Immune- -
588 002	
	Turbidimetry
	Rheumatoid Factors (RF) 2 Reagents
518 000	
518 001	
518 002	
518 003	
518 004	
518 005	
561001	
598001	
ZL-598 001	
	Rheumatoid Factor (RF)
D-838 000	
D-838 001	
D-838 002	Rheumatoid Factor (RF)
518 001	
518 002	
518 003	
518 004	
518 005	
518 006	



D-853 001	Rheumatoid Factor (RF) Turbilatex
598 001	RHEUMATOID FACTOR (RF)ImmunoTurbidimetry 3rd Generation (Aggregated human IgG method)
561 001	RHEUMATOID FACTOR (RF) Turbi - Latex
545 001 ZL-545 001	CRP/hs(C- Reactive protein)
340 001	ASO Control
343 001	CRP Control
405 001	D-Dimer Control Set
353 001	Microalbumin Control set
396 001	25-OH Vitamin D Control Set
344 001	RF Control
608 001	Immunology Control
608 002	Immunology Control
606 001	Immunology Control
606 002	Immunology Control
345 001	ASO Standard Super High
347 000	CRP Standard Super High
347 001	CRP Standard Super High
402 001	D-Dimer Calibrator
354 001	Fibrinogen Standard
352 001	Microalbumin Standard
604 001	Protein Standard High
604 002	Protein Standard High
387 001	Specific Protein Standard
393 001	25-OH Vitamin D Calibrator Set
349 001	RF Standard Super High
1176 001	HCG One Step pregnancy Test
1176 002	HCG One Step pregnancy Test
D-787 001	HCG Pregnancy Rapid Test Cassette (Serum, Plasma and Urine)



1178 001	HCG Pregnancy Rapid Test Cassette (Serum, Plasma and Urine)
1172 001	Troponin - I
1172 002	
D-789 001	Cardiac Troponin I Rapid Test Cassette (Serum/Plasma/Whole Blood)
D-626 001	Haemoglobin (Single Reagent) Drabkin's Solution
D-626 002	
D-625 000	Haemoglobin {Ready-To-Use} Drabkin's Solution
D-625 001	
D-625 002	
D-625 003	
D-660 001	Haemoglobin Drabkin's Solution
D-660 002	
D-749 001	Normal QC
D-749 002	
D-750 001	Abnormal QC
D-750 002	
	Multical
D-751001 D-751002	
610 001	Haemoglobin (Single Reagent)
610 002	
610 003	
610 004	
ZL-610 001	
611001	Haemoglobin {Ready to Use}
611002	
611003	



612 001	Haemoglobin Drabkin's Solution
612 002	
252 001	GGPD
253 001	G6PD - single reagent
D-655 001	Glucose-6-Phosphate Dehydrogenase (G-6-PD) Quantitative Assay
614 001	PT Reagent (SP-Normoplastin)
614 002	
624 000	Recoplastin ISI 1.0 PT Reagent
624 001	
624 002	
D-704 001	Liquid PT Reagent ISI 1.0
D-704002	
D-704003	
D-707 001	PT Reagent ISI 1.5
D-707 002	
D-707 003	
626 001	APTT Reagent (SP-UNICELIN)
626 002	
D-705 001	PTT Reagent
590 001	FIBRINOGEN
ZL-590 001	
D-708 001	Fibrinogen-IS Clauss Clotting Time Method
631 001	FIBRINOGEN-IS Clauss Clotting Time Method
631002	
585 001	D-Dimer
ZL-585 001	
D-856 001	D-Dimer Turbi latex



585 001	D-Dimer Turbi latex
585 002	
585 003	
585 004	
585 001-1	
585 002-1	
390 001	Specific Protein Control
1417 001	Blood Agar Base
1417 002	
1400 001	Brain Heart Infusion Agar
1400 002	
1401001	Brain Heart Infusion Broth
1401002	
1403 001	Cetrinide agar
1403 002	
1402 001	Cled agar with Bromothymol Blue
1402 002	
1419 001	Cled agar with Andrade Indicator
1419 002	
1404 001	Lactose Broth
1404 002	
1405001	MacConkey Agar
1405002	
1420 001	MACCONKEY BROTH
1420002	
1418 001	Mannitol Salt Agar
1418 002	
1406001	Mueller Hinton Agar
1406002	
1407 001	Nutrient Agar
1407 002	



1421001	Nutrient Broth
1421002	
1410 001	Plate count agar (Standard methods agar)
1410 002	
1408 001	PLO Agar
1408 002	
1409 001	PPO broth
1409 002	
1412 001	Sabouraud Dextrose Agar
1412 002	
1413001	Salmonella Shigella Agar (SS Agar)
1413002	
1416 001	Thioglycollate broth
1416002	
1422 001	Triple Sugar Iron Agar
1422 002	
1414 001	Tryptic soy agar
1414 002	
1415 001	Tryptic soy Broth
141S 002	
1452 001	Blood Culture Medium
1452 002	
1452 003	
1452 004	
1452 005	
1452 006	
D-940 001	
D-940 002	
D-940 003	
0-796 001	
1150001	Malaria Antigen Test (Whole Blood) For Plasmodium falciparum & vivax
1150002	Malaria Antigen Test Card



D-804 001	RPR Syphilis Test
725 001	RPR Syphilis Test
725 002	
725 000	
714 001	Urease test for H.Pylori
1154 001	S. Typhi/Para Typhi A Antigen
1154 002	
718 001	Widal Test (Salmonella Abs)
D-806000-O	Widal Test (Salmonella Ab)
D-806 000-H	
0-806 000-AH	
D-806 000-BH	
D-806 000-CO	
D-806 000-AO	
D-806 000-BO	
D-806 001	
D-806002	
718 000	Widal Test (Salmonella Ab)
718 001	
718 002	
718 003	
718 004	
718 005	
718 006	
718 002-0	
718 002-H	
718 002-AH	
718 002-BH	
718 002-AO	
D-792 001	Typhoid IgG/IgM Rapid Test-Cassette
1233 001	Typhoid Rapid Test Cassette (Serum/Plasma/Whole Blood)



710001	Brucella A/M
710002	
710 003	
710 004	
710005	
D-801001	Brucella A, Brucella M
D-802 001	
D-803 001	Rose Bengal Brucella Antigen
D-803 002	
711001	Rose Bengal Brucella Antigen
711002	
711003	
711004	
1192 001	HAV IgM Rapid Test Cassette(Serum/Plasma)
1200 001	SARS COV-2 QUALITATIVE Real Time PCR KIT (DUAL PROBE ASSAY)
1180001	H. pylori Ab Test
1184 001	H. pylori Ag Test
D-793 001	H. pylori Ab Rapid Test Cassette (Serum, Plasma and Whole Blood)
D-794 001	H. pylori Ag Rapid Test Cassette(Fecal Specimen)
D-788 001	HAV IgM Rapid Test Cassette(Serum/Plasma)
725 001	RPR Syphilis
725 002	RPR Syphilis
725 003	RPR Syphilis

