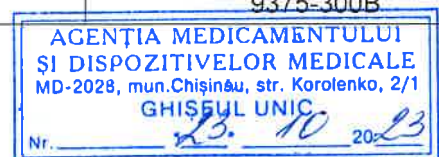


**Către Agenția Medicamentului
și Dispozitivelor Medicale**

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 01 din 29.09.2023

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 **MONOBIND Inc.** pentru introducerea și punerea la dispoziție pe piață a următoarelor produse:

DENUMIREA GENERIC	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells
AccuBind ELISA		
AccuLite CLIA		
Qsure Control		
Allergy & Anemia		
Ferritin Test System	2825-300A 2825-300B	2875-300A 2875-300B
Folate Test System	7525-300A 7525-300B	7575-300A 7575-300B
Immunoglobulin E (IgE) Test System	2525-300A 2525-300B	2575-300A 2575-300B
Transferrin Soluble Receptor (sTfR) Test System	8625-300A 8625-300B	8675-300A 8675-300B
Vitamin B-12 (Vit B12) Test System	7625-300A 7625-300B	7675-300A 7675-300B
Folate, Vitamin B-12 (Anemia Panel VAST) Test System	7825-300A 7825-300B	7875-300A 7875-300B
Autoimmune		
Anti-Cyclic Citrullinated Peptide IgG (Anti-CCP IgG) Test System	12725-300A 12725-300B	12775-300A 12775-300B
Anti-Thyroglobulin (Anti-Tg) Test System	1025-300A 1025-300B	1075-300A 1075-300B
Anti-Thyroperoxidase (Anti-TPO) Test System	1125-300A 1125-300B	1175-300A 1175-300B
Bone Metabolism & Growth		
Calcitonin Test System	9325-300A 9325-300B	9375-300A 9375-300B



Growth Hormone (hGH) Test System	1725-300A	1775-300A
	1725-300B	1775-300B
Parathyroid Hormone Intact (PTH) Test System	9025-300A	9075-300A
	9025-300B	9075-300B
Parathyroid Hormone (PTH) 3rd & 2nd Gen (VAST) Test System	10025-300A	10075-300A
	10025-300B	10075-300B
25(OH) Vitamin D Total Direct (Vit D-Direct) Test System	9425-300A	9475-300A
	9425-300B	9475-300B
Cancer Markers		
Alpha-Fetoprotein (AFP) Test System	1925-300A	1975-300A
	1925-300B	1975-300B
CA-125 Test System	3025-300A	3075-300A
	3025-300B	3075-300B
CA 15-3 Test System	5625-300A	5675-300A
	5625-300B	5675-300B
CA 19-9 Test System	3925-300A	3975-300A
	3925-300B	3975-300B
Carcinoembryonic Antigen (CEA) Test System	1825-300A	1875-300A
	1825-300B	1875-300B
Next Generation Carcinoembryonic Antigen (CEA-Next Gen) Test System	4625-300A	4675-300A
	4625-300B	4675-300B
Free β -Subunit Human Chorionic Gonadotropin (Free Beta hCG) Test System	2025-300A	2075-300A
	2025-300B	2075-300B
Cardiac Markers		
CK-MB Test System	2925-300A	2975-300A
	2925-300B	2975-300B
Digoxin (DIG) Test System	925-300A	975-300A
	925-300B	975-300B
High Sensitivity CRP (hs-CRP) Test System	3125-300A	3175-300A
	3125-300B	3175-300B
Myoglobin Test System	3225-300A	3275-300A
	3225-300B	3275-300B
Troponin I (cTnI) Test System	3825-300A	3875-300A
	3825-300B	3875-300B
Diabetes		
C-Peptide Test System	2725-300A	2775-300A
	2725-300B	2775-300B
Insulin Test System	2425-300A	2475-300A
	2425-300B	2475-300B
Rapid Insulin Test System	5825-300A	
	5825-300B	
Insulin - C-Peptide (Diabetes Panel VAST)	7325-300A	7375-300A
	7325-300B	7375-300B
Endocrine		
Adrenocorticotrophic hormone (ACTH) Test System	10625-300A	10675-300A
Aldosterone Test System	10125-300A	10175-300A
Leptin Test System	10825-300A	10875-300A
Fertility & Prenatal		

Anti-Müllerian Hormone (AMH) Test System	9725-300A 9725-300B	9775-300A 9775-300B
Folicle Stimulating Hormone (FSH) Test System	425-300A 425-300B	475-300A 475-300B
B-Human Chorionic Gonadotropin (hCG) Test System	825-300A 825-300B	875-300A 875-300B
B-Human Chorionic Gonadotropin Extended Range (hCG-XR) Test System	8825-300A 8825-300B	8875-300A 8875-300B
Rapid B-Human Chorionic Gonadotropin (Rapid -hCG) Test System	3325-300A 3325-300B	
Inhibin A Test System	9525-300A 9525-300B	9575-300A 9575-300B
Inhibin B Test System	9625-300A 9625-300B	9675-300A 9675-300B
Luteinizing Hormone (LH) Test System	625-300A 625-300B	675-300A 675-300B
Pregnancy Associated Plasma Protein – A Mass Units (PAPP-A Mass Units) Test System	12625-300A 12625-300B	12675-300A 12675-300B
Prolactin Hormone (PRL) Test System	725-300A 725-300B	775-300A 775-300B
Prolactin Hormone Sequential (PRLs) Test System	4425-300A 4425-300B	4475-300A 4475-300B
Follicle Stimulating Hormone (FSH), Human Chorionic Gonadotropin (hCG), Prolactin (PRLs), Luteinizing Hormone (LH), (Fertility Panel VAST) Test System	8325-300B 8325-300D 8325-300E	8375-300B 8375-300D 8375-300E
Alpha-Fetoprotein (AFP), Human Chorionic Gonadotropin (hCG), Unconjugated Estriol (u- E3) (Triple Screen Panel VAST) Test System	8525-300A 8525-300B	8575-300A 8575-300B
Infectious Diseases		
Anti-H. Pylori IgG (H. Pylori Ab IgG) Test System	1425-300A 1425-300B	1475-300A 1475-300B
Anti-H. Pylori IgM (H. Pylori Ab IgM) Test System	1525-300A 1525-300B	1575-300A 1575-300B
Anti-H. Pylori IgA (H. Pylori Ab IgA) Test System	1625-300A 1625-300B	1675-300A 1675-300B
Anti-SARS-CoV-2 (COVID-19) IgG Test System	11925-300A 11925-300B	11975-300A 11975-300B
Anti-SARS-CoV-2 (COVID-19) IgM Test System	11725-300A 11725-300B	11775-300A 11775-300B
Anti-SARS-CoV-2 (COVID-19) IgA Test System	11825-300A 11825-300B	11875-300A 11875-300B
Anti-SARS-CoV-2 (COVID-19) S1-RBD IgG Test System	12525-300A 12525-300B	12575-300A 12575-300B
D-Dimer Test System	12025-300A 12025-300B	12075-300A 12075-300B
Interleukin-6 (IL-6) Test System	13225-300A 13225-300B	13275-300A 13275-300B
Procalcitonin (PCT) Test System	9225-300A 9225-300B	9275-300A 9275-300B
Neonatal		
Neonatal 17OHP (N-17OHP) Test System	5525-300A 5525-300B	

Neonatal (N-T4) Thyroxine Test System	2625-300A 2625-300B	
Neonatal TBG (N-TBG) Test System	8925-300A 8925-300B	
Neonatal TSH (N-TSH) Test System	3425-300A 3425-300B 3425-300D 3425-300E	
Steroid		
Androstenedione (ANST) Test System	12425-300A 12425-300B	12475-300A 12475-300B
Cortisol Test System	3625-300A 3625-300B	3675-300A 3675-300B
Dehydroepiandrosterone (DHEA) Test System	7425-300A 7425-300B	7475-300A 7475-300B
Dehydroepiandrosterone Sulfate (DHEA-S) Test System	5125-300A 5125-300B	5175-300A 5175-300B
Estrone (E1) Test System	10325-300A 10325-300B	10375-300A 10375-300B
Estradiol (E2) Test System	4925-300A 4925-300B	4975-300A 4975-300B
Unconjugated Estiol (u-E3) Test System	5025-300A 5025-300B	5075-300A 5075-300B
Progesterone Test System	4825-300A 4825-300B	4875-300A 4875-300B
17-OH Progesterone (17-OHP) Test System	5225-300A 5225-300B	5275-300A 5275-300B
17-OH Progesterone SI (17-OHP-SI) Test System	9925-300A 9925-300B	9975-300A 9975-300B
Sex Hormone Binding Globulin (SHBG) Test System	9125-300A 9125-300B	9175-300A 9175-300B
Testosterone Test System	3725-300A 3725-300B	3775-300A 3775-300B
Free Testosterone Test System	5325-300A 5325-300B	5375-300A 5375-300B
Thyroid		
Total Triiodothyronine (tT3) Test System	125-300A 125-300B 125-300D 125-300E	175-300A 175-300B 175-300D 175-300E
Free Triiodothyronine (fT3) Test System	1325-300A 1325-300B 1325-300A 1325-300B	1375-300A 1375-300B 1375-300D 1375-300E
Total Triiodothyronine (tT3 SBS) Test System	8125-300A 8125-300B	8175-300A 8175-300B
Rapid Total Triiodothyronine (Rapid -tT3) Test System	11225-300A 11225-300B	
T3-Uptake (T3U) Test System	525-300A 525-300B	575-300A 575-300B
Thyroxine (tT4) Test System	225-300A 225-300B 225-300D 225-300E	275-300A 275-300B 275-300D 275-300E

Free Thyroxine (fT4) Test System	1225-300A 1225-300B 1225-300D 1225-300E	1275-300A 1275-300B 1275-300D 1275-300E
Total Thyroxine (tT4 SBS) Test System	8225-300A 8225-300B	8275-300A 8275-300B
Rapid Total Thyroxine (Rapid-tT4) Test System	11125-300A 11125-300B	
Thyrotropin (TSH) Test System	325-300A 325-300B 325-300D 325-300E	375-300A 375-300B 375-300D 375-300E
Rapid TSH Test System	6025-300A 6025-300B	6075-300A 6075-300B
Thyroxine-Binding Globulin (TBG) Test System	3525-300A 3525-300B	3575-300A 3575-300B
Thyroglobulin (Tg) Test System	2225-300A 2225-300B	2275-300A 2275-300B
Total Triiodothyronine (tT3), Total Thyroxine (tT4) & Thyroid Stimulating Hormone (TSH) (Thyroid Panel VAST) Test System	8025-300B 8025-300D 8025-300E	8075-300B 8075-300D 8075-300E
Free Triiodothyronine (fT3), Free Thyroxine (fT4) & Thyroid Stimulating Hormone (TSH) (Free Thyroid Panel VAST) Test System	7025-300B 7025-300D 7025-300E	7075-300B 7075-300D 7075-300E
Miscellaneous Controls		
Anti-H. Pylori Control (IgG, IgM, IgA) – Positive & Negative		
Anti-Tg & Anti-TPO Control – Positive & Negative		
Maternal Control – (AFP, uE3, hCG, Free beta hCG) Tri Level		
TBG Control – Tri-Level		
Tg Control – Tri-Level		
Tumor Marker Control – (CA 125, CA 15-3, CA 19-9) Tri-Level		
Miscellaneous Instruments		
Autoplex® ELISA & CLIA Analyzer		
Autoplex® G2 ELISA & CLIA Analyzer		
Autoplex® G3 ELISA & CLIA Analyzer		
NeoEldex® ELISA Analyzer		
Impulse® 3 CLIA Analyzer		
NeoLumax® CLIA Analyzer		
LuMatic® CLIA Analyzer		
PrisMatic® ELISA Analyzer		
PlateWash - Immunoassay Washer		
TITIN® ELISA & CLIA Analyzer		
TITIN® ELISA Analyzer		
TITIN-s® ELISA & CLIA Analyzer		
TITIN-s® ELISA Analyzer		

Se anexează următoarele acte:

Notificarea pentru înregistrarea dispozitivelor medicale;

Declarația pe proprie răspundere;

Declarația de conformitate;

Scrisoarea de Autorizare;

Certificat CE.

Data 29. 09. 2023

Semnătura 

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: 7801 din 23.10.2023
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	Cerlat Marin bioinginer
Semnătura persoanei responsabile	Cerlat