

Către Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 01 din 05.09.2023

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 **VACUTEST KIMA SRL** pentru introducerea și punerea la dispoziție pe piață a următoarelor produse:

Device Name
KIMASED RACK FOR ESR READING TUBES
KIMASED AUTO 20, ESR autoanalyzer 20 tubes positions.
KIMASED AUTO 60, ESR autoanalyzer 60 tubes positions.
KIMASED TUBES (ESR) Sodium citrate 3.8%, 12x118 mm, 2ml/1.6 ml
ESR TUBES Sodium citrate 3.8% 13x75mm (IN) 2ml/1,6ml
ESR TUBES Sodium citrate 3.8% 13x75mm standart 2ml/1,6ml
VACUUM CLOT ACTIVATOR TUBES
VACUUM CLOT ACTIVATOR TUBES 13X75mm, 2ml
VACUUM CLOT ACTIVATOR TUBES 13x75mm, 3ml
VACUUM CLOT ACTIVATOR TUBES 13x75mm, 4ml
VACUUM CLOT ACTIVATOR TUBES 13x100mm, 6ml
VACUUM CLOT ACTIVATOR TUBES 16x100mm, 9ml
VACUUM GEL AND CLOT ACTIVATOR TUBES
GEL AND CLOT ACTIVATOR TUBES 13x75mm, 2ml
GEL AND CLOT ACTIVATOR TUBES 13x75mm, 3,5ml
GEL AND CLOT ACTIVATOR TUBES 13x100mm, 5ml
GEL AND CLOT ACTIVATOR TUBES 16x100mm, 8ml
VACUUM GRANULES AND CLOT ACTIVATOR TUBES
GRANULES AND CLOT ACTIVATOR TUBES 13x75mm, 3,5ml
GRANULES AND CLOT ACTIVATOR TUBES 13x75mm, 5ml
GRANULES AND CLOT ACTIVATOR TUBES 16x100mm, 8ml
VACUUM GEL AND LITHIUM HEPARIN TUBES
VACUUM GEL AND LITHIUM HEPARIN TUBES 13x75mm, 3,5ml
VACUUM GEL AND LITHIUM HEPARIN TUBES 13x100mm, 5ml
VACUUM GEL AND LITHIUM HEPARIN TUBES 16x100mm, 8ml
VACUUM GEL AND LITHIUM HEPARIN TUBES

VACUUM HEPARIN TUBES

HEPARIN TUBES 13x75mm, 2ml

HEPARIN TUBES 13x75mm, 4ml

HEPARIN TUBES 13x100mm, 6ml

HEPARIN TUBES 16x100mm, 9ml

VACUUM K2EDTA/K3EDTA TUBES

VACUUM EDTA TUBES 13x75mm, 1ml

VACUUM EDTA TUBES 13x75mm, 2ml

VACUUM EDTA TUBES 13x75mm, 3ml

VACUUM EDTA TUBES 13x75mm, 4ml

VACUUM EDTA TUBES 13x100mm, 6ml

VACUUM EDTA TUBES 16x100mm, 9ml

VACUUM BUFFERED SODIUM CITRATE TUBES

VACUUM BUFFERED SODIUM CITRATE TUBES 3,2% 13x75mm, 2ml/1,8ml

VACUUM BUFFERED SODIUM CITRATE TUBES 3,8% 13x75mm, 2ml/1,8ml

VACUUM BUFFERED SODIUM CITRATE TUBES 3,2% 13x75mm, 2,5ml/2,25ml

VACUUM BUFFERED SODIUM CITRATE TUBES 3,8% 13x75mm, 2,5ml/2,25ml

VACUUM BUFFERED SODIUM CITRATE TUBES 3,2% 13x75mm, 3,5ml/3,15ml

VACUUM BUFFERED SODIUM CITRATE TUBES 3,8% 13x75mm, 3,5ml/3,15ml

VACUUM BUFFERED SODIUM CITRATE TUBES 3,2% 13x75mm, 4ml/3,6ml

VACUUM BUFFERED SODIUM CITRATE TUBES 3,8% 13x75mm, 4ml/3,6ml

VACUUM BUFFERED SODIUM CITRATE TUBES 3,8% 13x75mm, 4,5ml/4,05ml

VACUUM BUFFERED SODIUM CITRATE TUBES 3,2% 13x75mm, 5ml/4,5ml

VACUUM BUFFERED SODIUM CITRATE TUBES 3,8% 13x75mm, 5ml/4,5ml

VACUUM NO ADDITIVE TUBES

VACUUM NO ADDITIVE TUBES 13x75mm, 4ml

VACUUM NO ADDITIVE TUBES 13x100mm, 6ml

VACUUM NO ADDITIVE TUBES 16x100mm, 9ml

KIMAmikroTEST VACUUM STERILE TUBES FOR PEDIATRIC BLOOD TAKINGS

K2EDTA 250mkl

K2EDTA 500mkl

K3EDTA 250mkl

K3EDTA 500mkl

K3EDTA 1000mkl

NO ADDITIVE 250-500mkl

CLOT ACTIVATOR 500mkl

GEL+CLOT ACTIVATOR 800mkl

LOTHIUM HEPARIN 500mkl

LOTHIUM HEPARIN 800mkl

SODIUM CITRATE 3,2% 500mkl

SODIUM CITRATE 3,8% 500mkl

CAPILLARY TEST TUBES FOR PEDIATRIC BLOOD COLLECTIONS

K2EDTA 200mkl

K3EDTA 200mkl

CLOT ACTIVATOR 200mkl

URINE COLLECTION TUBES CONICAL TEST TUBES
URINE COLLECTION TUBES 16x100mm, 9,5ml
URINE COLLECTION TUBES CYLINDRICAL TEST TUBES
URINE COLLECTION TUBES 13x75mm, 4ml
URINE COLLECTION TUBES 13x100mm, 6ml
URINE COLLECTION TUBES 16x100mm, 9ml
URINE COLLECTION TUBES 16x100mm, 6ml

Se anexează următoarele acte:

Notificarea pentru înregistrarea dispozitivelor medicale;

Declarația pe proprie răspundere;

Declarația de conformitate;

Scrisoarea de Autorizare;

Data 05.09.2023

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. 7557 din 28.09.2023
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	Glavatchi D'omirice
Semnătura persoanei responsabile	G'D'S