

**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
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GRANULES AND CLOT ACTIVATOR TUBES 13x75mm, 3,5ml
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HEPARIN TUBES 13x100ml, 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
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VACUUM NO ADDITIVE TUBES 13x75mm, 4ml
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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
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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	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

DECLARATIE PE PROPRIE RĂSPUNDERE

Solicitant: „GBG-MLD” SRL, cu sediul în mun. Chișinău, str. Albisoara 64/2,

declar pe proprie răspundere, cunoscând prevederile art. 352¹, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru înregistrarea dispozitivelor producătorului **VACUTEST KIMA SRL** pentru introducerea și punerea la dispoziție pe piață a următoarelor produse:

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URINE COLLECTION TUBES 16x100mm, 6ml

Sunt autentice și corespund realității.

Cristina GUȚU, Șef Secție „GBG-MLD” SRL

Semnătura _____

Data _____





www.vacutestkima.it

DICHIARAZIONE DI CONFORMITÀ CE

EC DECLARATION OF CONFORMITY

conforme all'Allegato III della Direttiva 98/79/CE "Dispositivi Medico-Diagnostici In Vitro" e s.m.i.
according to Annex III of the Directive 98/79/EC on "In Vitro Diagnostic Medical Devices" as amended

fabbricante
manufacturer

VACUTEST KIMA S.r.l. - articoli per laboratori analisi
disposable labware

indirizzo
address

Via dell'Industria, 12
35020 Arzergrande (PD) - Italia

telefono
phone

+39-049-9720624

fax
fax

+39-049-9720182

posta elettronica
e-mail

info@vacutestkima.it

identificazione dei prodotti
product identification

Sistema per microprelievi di sangue
Micro blood collection system

nome commerciale
brand name

"kima μ test"

classificazione dei prodotti
product classification

dispositivi diversi da quelli elencati nell'Allegato II della Direttiva 98/79/CE e s.m.i.
devices other than those mentioned in Annex II of the Directive 98/79/EC as amended

Si dichiara

sotto la propria responsabilità che tutti i dispositivi sopraelencati rispettano le disposizioni applicabili della Direttiva 98/79/CE e s.m.i. "Dispositivi Medico-Diagnostici In Vitro".

Tutta la documentazione tecnica richiesta dall'Allegato III della succitata Direttiva e comprovante il rispetto dei Requisiti Essenziali di cui all'Allegato I della Direttiva, è conservata a cura del Fabbricante

Hereby we declare

under our sole responsibility that the above mentioned devices meet the applicable provisions of the Directive 98/79/EC as amended on "In Vitro Diagnostic Medical Devices".

All the supporting documents, as required by Annex III of the 98/79/EC Directive, in order to prove conformity to the Essential Requirements as listed in Annex I, are retained under the premises of the Manufacturer

luogo e data
place and date

Arzergrande, 19/02/2021

firma
signature

Assicuratore Qualità / Quality Manager
Giovanni Chiarin





www.vacutestkima.it

DICHIARAZIONE DI CONFORMITÀ CE

EC DECLARATION OF CONFORMITY

conforme all'Allegato III della Direttiva 98/79/CE "Dispositivi Medico-Diagnostici In Vitro" e s.m.i.
according to Annex III of the Directive 98/79/EC on "In Vitro Diagnostic Medical Devices" as amended

fabbricante **VACUTEST KIMA S.r.l. - articoli per laboratori analisi**
manufacturer **disposable labware**

indirizzo **Via dell'Industria, 12**
address **35020 Arzergrande (PD) - Italia**

telefono **+39-049-9720624**
phone

fax **+39-049-9720182**
fax

posta elettronica **info@vacutestkima.it**
e-mail

identificazione dei prodotti
product identification

**Sistema di prelievo di sangue e altri liquidi biologici
mediante provette con vuoto predeterminato in plastica
"VACUTEST PLAST".**

**"VACUTEST PLAST" vacuum blood and biological liquids
collection tubes in plastic.**

nome commerciale
brand name

"VACUTEST PLAST"

classificazione dei prodotti
product classification

**dispositivi diversi da quelli elencati nell'Allegato II della Direttiva 98/79/CE e s.m.i.
devices other than those mentioned in Annex II of the Directive 98/79/EC as amended**

Si dichiara

sotto la propria responsabilità che tutti i dispositivi sopraelencati rispettano le disposizioni applicabili della Direttiva 98/79/CE e s.m.i. "Dispositivi Medico-Diagnostici In Vitro".

Tutta la documentazione tecnica richiesta dall'Allegato III della succitata Direttiva e comprovante il rispetto dei Requisiti Essenziali di cui all'Allegato I della Direttiva, è conservata a cura del Fabbricante

Hereby we declare

under our sole responsibility that the above mentioned devices meet the applicable provisions of the Directive 98/79/EC as amended on "In Vitro Diagnostic Medical Devices".

All the supporting documents, as required by Annex III, in order to prove conformity to the Essential Requirements as listed in Annex I, are retained under the premises of the Manufacturer

luogo e data
place and date

Arzergrande, 17/02/2021

firma
signature

**Assicuratore Qualità / Quality Manager
Giovanni Chiarin**



DICHIARAZIONE DI CONFORMITA' UE
EU DECLARATION OF CONFORMITY

conforme all'Allegato IV del Regolamento (UE) 2017/746 "Dispositivi medico-diagnostici in vitro"
according to Annex IV of the Regulation (EU) 2017/746 "In vitro diagnostic medical devices"

fabbricante **VACUTEST KIMA S.R.L.**
manufacturer **articoli per laboratori analisi - disposable labware**

N° registrazione unico **IT-MF-000021268**
SRN

indirizzo **Via dell'Industria, 12,**
address **35020 ARZERGRANDE (PD) - ITALIA**

telefono **+39-0499719511** fax **+39-0499719543** posta elettronica **info@vacutestkima.it**
phone e-mail

Identificazione dei prodotti **KIMASED RACK 10**

Product identification **KIMASED RACK for ESR reading tubes**

Destinazione d'uso **PORTA PROVETTE KIMASED DA UTILIZZARE PER LA LETTURA DELLA VES**
IN 30 MIN

Intended use **KIMASED RACK TO BE USED TO READ ESR IN 30 MIN**

BASIC UDI-DI **803363817RACKD6**

CND **W050101010201**

numero di catalogo **142600** numero di lotto scadenza
part number batch number expiry date

classificazione dei prodotti **dispositivi non sterili rientranti nella classe A del regolamento 2017/746, conforme alla regola 5**
product identification **non sterile devices included in the class A regulation (EU) 2017/746, according to rule 5**



Si dichiara

sotto la propria esclusiva responsabilità che tutti i dispositivi sopraelencati rispettano le disposizioni applicabili dal regolamento 2017/746 Dispositivi Medico-Diagnostici In Vitro.

La documentazione tecnica richiesta dal succitato regolamento e quella comprovante il rispetto dei Requisiti generali di sicurezza e prestazione di cui all'Allegato I del Regolamento, sono conservati a cura del Fabbricante

Hereby we declare

Under our sole responsibility that the above mentioned devices meet the applicable provisions of the Regulation (EU) 2017/746 on "In vitro diagnostic medical devices"

The technical documentation, as required by Regulation (EU) 2017/746 and documents in order to prove conformity to general safety and performance requirements as listed in Annex I, are retained under the premises of the Manufacturer

luogo e data
place and date **ARZERGRANDE, 18/11/2022**

firma
signature **VACUTEST KIMA S.R.L.**
Quality Assurance
Giovanni Chiarin



www.vacutestkima.it

DICHIARAZIONE DI CONFORMITÀ CE EC DECLARATION OF CONFORMITY

conforme all'Allegato III della Direttiva 98/79/CE "Dispositivi Medico-Diagnostici In Vitro" e s.m.i.
according to Annex III of the Directive 98/79/EC on "In Vitro Diagnostic Medical Devices" as amended

fabbricante
manufacturer

**VACUTEST KIMA S.r.l. - articoli per laboratori analisi
disposable labware**

indirizzo
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posta elettronica
e-mail

info@vacutestkima.it

identificazione dei prodotti
product identification

Autoanalizzatore per provette KIMASED

KIMASED Tubes AUTOANALYZER

nome commerciale
brand name

"KIMASED AUTO 60" "KIMASED AUTO 20"

classificazione dei prodotti
product classification

**dispositivi diversi da quelli elencati nell'Allegato II della Direttiva 98/79/CE e s.m.i.
devices other than those mentioned in Annex II of the Directive 98/79/EC as amended**

Si dichiara

sotto la propria responsabilità che tutti i dispositivi sopraelencati rispettano le disposizioni applicabili della Direttiva 98/79/CE e s.m.i. "Dispositivi Medico-Diagnostici In Vitro".

Tutta la documentazione tecnica richiesta dall'Allegato III della succitata Direttiva e comprovante il rispetto dei Requisiti Essenziali di cui all'Allegato I della Direttiva, è conservata a cura del Fabbricante

Hereby we declare

under our sole responsibility that the above mentioned devices meet the applicable provisions of the Directive 98/79/EC as amended on "In Vitro Diagnostic Medical Devices".

All the supporting documents, as required by Annex III of the 98/79/EC Directive, in order to prove conformity to the Essential Requirements as listed in Annex I, are retained under the premises of the Manufacturer

luogo e data
place and date

Arzergrande, 23/08/2021

**Assicuratore Qualità / Quality Manager
Giovanni Chiarin**

firma
signature

VACUTEST KIMA s.r.l.

Via dell'Industria, 12
35020 ARZERGRANDE (PD)
Partita IVA 03450130285



Arzergrande, 06/07/2023

To: Agentia Medicamentului si Dispozitivelor Medicale

We, "VACUTEST KIMA SRL – Via dell'Industria, 12 – 35020 Arzergrande (PD) - ITALY, assign "GBG-MLD" SRL, having a registered office at Str. Albisoara 64/2, Chisinau MD -2005, Moldova, as **authorized representative** in correspondence with the conditions if directive 93/42/EEC, 98/79/EEC and 90/385/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

VACUTEST KIMA s.r.l.
Via dell'Industria, 12
35020 ARZERGRANDE (PD)
Partita IVA 03450130285


Monica Vianello

Legal Representative



Device Name
KIMASED RACK FOR ESR READING TUBES
KIMASED AUTO 20, ESR autoanalyzer 20 tubes positions.
KIMASED AUTO 60, ESR autoanalyzer 60 tubes positions.
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