

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. ECO-08/24-2 din 24.08.2023

Solicitantul Ecochimie SRL, cu sediul Republica Moldova, mun. Chișinău, str. Valea Crucii 2, of. 85, tel./fax: 022109111, e-mail info@ecochimie.md, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)
1	MF2031001	Perie curatare eprubete, maner din material galvanizat, marime: Large, Medium, Small

Se anexează următoarele acte:

1. Autorizație de la producător
2. Declarație de conformitate CE
3. Certificat ISO13485
4. Lista de bunuri
5. Catalog
6. Declarație pe proprie răspundere

Data 24.08.2023

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	



为了您的微笑
For Your Smile

Letter of Authorization

We, Ningbo MFLAB Medical Instruments Co., Ltd,

based in No. 508, Yindong Road(N), Yinzhou Economic Development Zone, 345145
Ningbo, R.P. China,

assign Ecochimie SRL,

based in Republic of Moldova, mun. Chisinau, str. Valea Crucii 2, of. 85,

as **authorized representative** in correspondence with the conditions of directive
93/42/EEC, 98/79/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, and to perform Essential Duties required by Law No. 102 09.06.2017 regarding medical devices.

Company Seal: Ningbo MFLAB Medical Instruments Co., Ltd

Authorized Signature: 李雅博

Date: April, 28th 2022



EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: Ningbo MFLAB Medical Instruments Co., Ltd.
No.508, Yindong Road(N), Yinzhou Economic
Development Zone, Ningbo315145, China

We declare under our sole responsibility that
the medical device: Test tube brushe

of class: I
UMDNS: 10500
according to annex IX of directive 93/42/EEC

meets the provisions of the directive 93/42/EEC Annex VII and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device.

Conformity assessment procedure: 93/42/EEC Annex VII

Registration No.: SX 601503630001

Notified Body: TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg

Ningbo 2023-07-14

Place, date

宁波蓝柏医疗器械有限公司
NINGBO MFLAB MEDICAL INSTRUMENTS CO., LTD
Yazeng Li General Manager
Name and function



Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1	MF2031001	Perie	MFLab	Perie curatare eprubete, maner din material galvanizat, marime: Large, Medium, Small	





Code	Description	Material	Packing
MF88111615	Screw tubes serological bakelite cap with silicon rubber gasket, Autoclavable, round bottom, Vol. 15ml, Dim.: Φ16x150mm, 0.8-1.0mm thick wall	Borosilicate Glass	250pcs/box, 2000pcs/ctn, 43.5x34.5x38cm
MF88211615	Screw tubes serological bakelite cap with silicon rubber gasket, Autoclavable, flat bottom, Vol. 15ml, Dim.: Φ16x150mm, 0.8-1.0mm thick wall	Borosilicate Glass	250pcs/box, 2000pcs/ctn, 43.5x34.5x38cm
MF88112030	Screw tubes serological bakelite cap with silicon rubber gasket, Autoclavable, round bottom, Vol. 30ml, Dim.: Φ20x150mm, 0.8-1.0mm thick wall	Borosilicate Glass	250pcs/box, 2000pcs/ctn, 43.5x34x47.5cm
MF88212030	Screw tubes serological bakelite cap with silicon rubber gasket, Autoclavable, flat bottom, Vol. 30ml, Dim.: Φ20x150mm, 0.8-1.0mm thick wall	Borosilicate Glass	250pcs/box, 2000pcs/ctn, 43.5x34x47.5cm
MF88242825	Makarthy tube aluminum cap with silicon rubber gasket, Autoclavable, flat bottom, Vol. 25ml, Dim. Φ28x85mm, 1.0-1.2mm thick wall	Borosilicate Glass	100pcs/box, 600pcs/ctn, 55x33x29cm
MF2030005C	Test tube, Screw cap, round bottom, Vol. 5ml	Cap(PE) Tube(PP)	200pcs/pack, 4000pcs/ctn

TEST TUBE BRUSH

MF2031001
Material: Wool, Bristle, Nylon
Brush head shape: Fan-shaped, Bar head
Handle: Wire material
Size: Large, Medium, Small

TUBE STOPPERS Flange Tpye



Code	Description	Material	Packing
MF87010012N	Diam. Φ12mm, Color, Neutral	PE	1000pcs/bag, 20000pcs/ctn, 64x28x29cm
MF87010012W	Diam. Φ12mm, Color, White	PE	1000pcs/bag, 20000pcs/ctn, 64x28x29cm
MF87010012R	Diam. Φ12mm, Color, Red	PE	1000pcs/bag, 20000pcs/ctn, 64x28x29cm
MF87010012M	Diam. Φ12mm, Color, Mauve	PE	1000pcs/bag, 20000pcs/ctn, 64x28x29cm
MF87010012B	Diam. Φ12mm, Color, Blue	PE	1000pcs/bag, 20000pcs/ctn, 64x28x29cm
MF87010012G	Diam. Φ12mm, Color, Green	PE	1000pcs/bag, 20000pcs/ctn, 64x28x29cm

Code	Description	Material	Packing
MF87120013N	Diam. Φ13mm, Color, Neutral	PE	1000pcs/bag, 20000pcs/ctn, 64x28x38cm
MF87010013W	Diam. Φ13mm, Color, White	PE	1000pcs/bag, 20000pcs/ctn, 64x28x38cm
MF87010013R	Diam. Φ13mm, Color, Red	PE	1000pcs/bag, 20000pcs/ctn, 64x28x38cm
MF87010013M	Diam. Φ13mm, Color, Mauve	PE	1000pcs/bag, 20000pcs/ctn, 64x28x38cm
MF87010013B	Diam. Φ13mm, Color, Blue	PE	1000pcs/bag, 20000pcs/ctn, 64x28x38cm
MF87010013G	Diam. Φ13mm, Color, Green	PE	1000pcs/bag, 20000pcs/ctn, 64x28x38cm

Code	Description	Material	Packing
MF87010016N	Diam. Φ16mm, Color, Neutral	PE	1000pcs/bag, 20000pcs/ctn, 64x28x37cm
MF87020016W	Diam. Φ16mm, Color, White	PE	1000pcs/bag, 20000pcs/ctn, 64x28x37cm
MF87020016R	Diam. Φ16mm, Color, Red	PE	1000pcs/bag, 20000pcs/ctn, 64x28x37cm
MF87020016M	Diam. Φ16mm, Color, Mauve	PE	1000pcs/bag, 20000pcs/ctn, 64x28x37cm
MF87020016B	Diam. Φ16mm, Color, Blue	PE	1000pcs/bag, 20000pcs/ctn, 64x28x37cm
MF87020016G	Diam. Φ16mm, Color, Green	PE	1000pcs/bag, 20000pcs/ctn, 64x28x37cm

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: ECOCHIMIE SRL, cu sediul Republica Moldova, mun. Chișinău, str.
Valea Crucii 2, of. 85,

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 notificarea dispozitivului medical:

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)
1	MF2031001	Perie curatare eprubete, maner din material galvanizat, marime: Large, Medium, Small

Se anexează următoarele acte:

1. Autorizație de la producător
2. Declarație de conformitate CE
3. Certificat ISO 13485
4. Lista de bunuri
5. Catalog

Sunt autentice și corespund realității.

Iurcu Nicolae
Director

Semnătura _____
Data 24 august 2023

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Ningbo MFLAB Medical Instruments
Co., Ltd.
No.508,Yindong Road(N)
Yinzhou Economic Development
Zone
315145 Ningbo
P.R. China**

has established and applies a quality management system for medical devices
for the following scope:

**Manufacture and Distribution of Medical Devices
(see attachment for products included)**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-07-21

Certificate Registration No.: SX 60150363 0001

An audit was performed. Report No.: 15050519 014

This Certificate is valid until: 2023-07-20

Certification Body



Date 2020-07-21



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60150363 0001
Report No.: 15050519 014

Organization: Ningbo MFLAB Medical Instruments
Co., Ltd.
No.508,Yindong Road(N)
Yinzhou Economic Development
Zone
315145 Ningbo
P.R. China

Scope:

Products:

- Oxygen Masks for Single Use
- Venturi Masks for Single Use
- Nebulizer Masks for Single Use
- Oxygen Masks with Reservoir Bags for Single Use
- Tracheostomy Masks for Single Use
- Nebulizers with Mouth-pieces
- Nasal Oxygen Cannulas
- Oxygen Connection Tubings
- Connecting Tubes with Yankauer Handle
- Anesthesia Masks
- Laryngeal Mask Airways
- Bougies
- Resuscitation Masks
- Silicone/SEBS/PVC Manual Resuscitators
- Endotracheal Tubes
- Reinforced Endotracheal Tubes
- Tracheostomy Tubes
- Nelaton Catheters

Certification Body



Date: 2020-07-21

Fuxiu Sheng



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60150363 0001
Report No.: 15050519 014

Organization: Ningbo MFLAB Medical Instruments
Co., Ltd.
No.508,Yindong Road(N)
Yinzhou Economic Development
Zone
315145 Ningbo
P.R. China

Scope:

Products:

- Stomach Tubes
- Suction Catheters
- Sterile Three-way Stopcocks for Single Use
- Disposable Breathing Circuits
- Breathing System Filters
- Heat and Moisture Exchangers
- Sterile Urine Containers
- Rectal Tubes
- Oral Pharyngeal Airways
- Nasopharyngeal Airways
- Feeding Tubes
- Burette Infusion Sets
- Urinary Collection Bags for Single Use
- Cotton Tipped Applicators
- Swabs
- Peak Meters
- Plastic Sample Cups
- Disposable Vacuum Blood Tubes

Certification Body



Date: 2020-07-21



Fuxiu Sheng



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60150363 0001
Report No.: 15050519 014

Organization: Ningbo MFLAB Medical Instruments
Co., Ltd.
No.508,Yindong Road(N)
Yinzhou Economic Development
Zone
315145 Ningbo
P.R. China

Scope:

Products:

- Disposable Vacuum Blood Collection Systems
- Disposable Vaginal Speculums
- Micro Blood Collection Tubes
- Vacuum Urine Collection Sets
- Disposable Non Vacuum Blood Tubes
- Spacers for Aerosol
- Spirometers
- Disposable Labwares and Instruments for Medical Use
(Test Tubes, Tube Stoppers, Centrifuge Tubes,
Pipette Tips, Transfer Pipettes, Petri Dishes,
Containers (Measuring Cups, Urine Containers,
Specimen Containers)
- Disposable Connecting Extension Tubes
- Suction connecting Tubes
- Yankauer Handles
- Suction Poole Drains
- Umbilical Cord Clamps

Certification Body



Date: 2020-07-21

Fuxiu Sheng

