

## إخطار تسجيل مستلزم محلي

كل كشط او تغيير في البيانات يعتبر التسجيل لاغيا

\*يعد الاطلاع على القاتون رقم 127 لسنة 1955 بشأن مزاولة مهنة الصيدله والمعدل بالقاتون رقم 167 لسنة 1998 بشأن تسجيل المستلزمات الطبية و قاتون إنشاء هيئة الدواء المصرية رقم 151 لسنة 2019 و لائحته التنفيذية وبناء على قرار وزير الصحة والسكان رقم 213 لسنة 1998 والمعدل بالقرار رقم 542 لسنة 2007

تمت الموافقة على تسجيل المستلزم الطبي التالي ببياناته:

New registration / re- registration	Registration
Applicant name	يوروميد للصناعات الطبية
Entity Type	local
Applicant Address	المنطقة الحرة العامة - مدينة نصر - قطعة رقم 10 - بلوك - مدينة نصر أول - القاهرة (I)
First Issue date	08/12/2022
Expiry date of registration license	07/12/2032
Registration license number	R115125Lrc22V1
License number	LiMD2022014/0082004
Version number	1
Approved from	بناء على الاجراءات المتبعة في تسجيل المستلزمات الطبية
Approved date	07/12/2022
Medical device information	
Medical device category	anesthesia
Trade name	Euro-Infusion set with flash back
Medical device description	Sterile Infusion Set
Nomenclature code type	UMDN
Nomenclature code number	16649
The Intended use	. Surgically invasive short-term use - Used for the infusion set of I.V. Fluids and fluid derivatives. - Infusion sets are used for the controlled infusion of medications, typically over long periods of time. Infusion sets are used to connect the medication to the needle inserted into the patient. Infusion extension sets are also used to extend I.V lines without risk of contamination.
Adopted regulation	EU
Class	class IIa
Sterile/ non-Sterile	Sterile Packing
Is Dosage form	no
Sterilization method	Ethylene oxide gas
Shelf life (Months)	60

Arab Republic of Egypt  
Egyptian Drug Authority  
CA for Medical Devices  
General administration of Medical  
Device Registration  
administration of local medical devices  
registration



جمهورية مصر العربية  
هيئة الدواء المصرية  
الإدارة المركزية للمستلزمات الطبية  
الإدارة العامة لتسجيل المستلزمات  
الطبية  
إدارة تسجيل المستلزمات الطبية  
محلية

### Packaging

Description configuration	single unit packed in medical paper and PE/PP roll, packed 25 in PE bag and packed 500 Pcs outer carton
-Material of primary Pack	PE/PP roll & Medical paper
-No. of units per primary pack	1
-Material of Secondary Pack	PE
-No. of units per Secondary pack	25
-Material of Tertiary Pack	Carton
-No. of units per Tertiary pack	500
Storage Condition	Shall be stored in cool & dry place. -Do not exposure to heat or direct sunlight. -the Temperature limit from 15°C to 35°C. -Keep away from any source of ignition
Country of origin	Egypt Free Zone

### Manufacturer information

Manufacturer	Euromed For Medical Industries	Free Zone-Nasr City-Part no.10-Block (I)
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### Certificate information

#### CE certificate

Certificate no.:	Notified Body name:	Notified Body ID:	Issue date	Expiry date
EG20/2833	SGS Belgium NV	1639	28/10/2020	24/05/2024

#### ISO 13485:2016

Certificate no.:	Notified Body name:	Issue date	Expiry date
EG07/72442	SGS united kingdom Ltd	01/08/2022	16/07/2025

#### Free Sale Certificate

Certificate no.:	Issuance Authority:	Issue date:	Expiry date
PS/CLV/EBL/1158/2022-CEX	Spain	14/09/2022	—

#### Variant

Variant	(I.V 009) Euro-Infusion set with flash back 100cm/ (I.V 010) Euro Infusion set with flash back 110cm/ (I.V 011) Euro-Infusion set with flash back 120cm/ (I.V 012) Euro-Infusion set with flash back 125cm/ (I.V 013) Euro-Infusion set with flash back 140cm/ (I.V 014) Euro-Infusion set with flash back 130cm/ (I.V 015) Euro-Infusion set with flash back 150cm
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### Raw Material

Component	PVC Tube	Polyvinylchloride PVC medical grade
Component	spike cap	Polypropylene "P.P" medical grade
Component	spike	Acrylonitrile butadiene styrene "ABS" medical grade
Component	Drip chamber	Polyvinylchloride PVC medical grade
Component	Clamb roller	Polypropylene "PP" medical grade)
Component	Clamp body	Polypropylene "PP" medical grade
Component	Slip connector	Acrylonitrile butadiene styrene "ABS" medical grade
Component	Hypodermic needle	Stainless Steel304
Component	Flash back	latex free Rubber

11/11/11

مدير الإدارة: **د. البشير جلال**  
11/11/11

- ملاحظات:
- \* لا يسمح بالإعلان عن المستلزمات الطبية في أي من وسائل الاعلام إلا بعد الحصول على موافقة كتابية من هيئة الدواء المصرية المنشأة طبقاً للقانون رقم 151 لسنة 2019 و لائحته التنفيذية
  - \* تم إصدار هذا الاخطار وفقاً لشهادة الجودة الحاصل عليها المنتج. المصنع مسؤل مسؤلية كاملة عن صلاحية الجهاز او المستلزم وسلامته الفنية وأية عيوب أو أخطار تترتب على استخدامه تقع على مسؤليتهما الخاصة.
  - \* يعتبر هذا الإخطار بتسجيل المستلزم لاغياً:
  - 1- عدم التزام الشركة بوجود نظام بقبطة المستلزمات الطبية، وبمتابعة جميع أنشطته ومتطلباته وفقاً للدلائل الاسترشادية لنظام بقبطة المستلزمات الطبية مع إدارة مأمونية المستلزمات الطبية - مركز البقبطة الصيدلية المصري.
  - 2- عدم التزام الشركة بالإبلاغ عن أي إجراءات سحب (Recall) أو (FSN) أو (FSCA) تتم عالمياً، أو أي حوادث (Incidents) يتم رصدها في جمهورية مصر العربية إلى الإدارة العامة للقبطة الصيدلية - مركز البقبطة الصيدلية المصري، وفقاً للمدد الزمنية المحددة بالدلائل الاسترشادية لنظام بقبطة المستلزمات الطبية.
  - 3- في حالة عدم إحضار شهادة الجودة المجددة التاريخ لنفس المستلزم مع فاتورة الشحن.
  - \* لا يجوز التنازل عن هذا الاخطار إلا بناء على الشروط والإجراءات المحددة بالقرارات المنظمة

يعتمد  
رئيس الإدارة المركزية للمستلزمات الطبية  
د/ميريام بولس قسطندي  
11/11/11



يعتمد  
مدير عام الإدارة العامة لتسجيل  
د/نهى أسامة الحريري  
11/11/11


**Euro-Infusion Set with flash back**


**M.O.H Reg. No.**

REF I.V 011

B.N 22/142

LOT 22/302

 09-2022

 08-2027

**25 Pcs**

**Quality Manager  
Shimaa Rabeey**





Euromed for medical industries

# Euro-Infusion Set with flash back

20 drops = (1 ±0.1)ml

Non-toxic, Pyrogen free.

### General Description:

Convenient, easy to use, sharp spike with flexible drip chamber  
 Clear transparent and flexible drip chamber to see flow rate and allows an estimation of flow rate. Accurate flow control  
 Strong yellow clamp & wheel with provision to hold the tube for changing the fluid container without disturbing the flow rate.  
 Kink free & 100 cm transparent PVC tubing for easy visualization of flow rate, taper foot, as per International Standard.  
 Flush ball type latex free stopcock mechanism. Also available with a Y injection site (with or without  
 Luer)

Options of luer lock connector, needle available. Single use and non pyrogenic

### Intended Use:

Surgically invasive short term use  
 Used for the infusion set of T.V. fluids and fluid distribution.  
 Infusion sets are used for the controlled infusion of medications, typically over long periods of time. Infusion sets are used to  
 connect the medication to the needle inserted into the patient. Infusion extension sets are also used to extend  
 I.V. lines without risk of contamination.

### Indications:

Intravenous Infusion (Infusion set) is the fastest way to deliver medication or replace fluids throughout the body. Starting  
 infusions are solutions are administered into a vein through an infusion set that includes a plastic/glass vacuum bottle or bag  
 containing the solution to be administered.

### Intended Patient Population:

This product is used for pediatric patient and/or heart patient or kidney patient, also used for patients who need  
 small drops and small medicine and short interval.

### INSTRUCTION FOR USE:

- 1- Close the roller clamp
- 2- Remove spike protection
- 3- Insert spike into infusion set container
- 4- perform connections
- 5- Open clamp and permit fluid to flow in drip chamber & tubing. 6- Control fluid flow through roller clamp (flow regulator).
- 7- Close roller clamp (flow regulator) after finishing fluid transfer.
- 8- Medication may be added through latex injection site at end of tube. 9- Product is single use only, discard the product in safety  
 box.

### Sterilization:

Infusion set is sterilized by Euromed for Medical Industries, EO sterilization, biological indicator testing and aseptic process  
 are performed by Euromed for Medical Industries Company.

### Shelf life:

Following certification the product has 3 years shelf life, provided that it is stored in the original packaging in recommended  
 storage condition and that the packs are not damaged or exposed or tampered with in any way.

### WARNINGS:

Product is single use only. Re-use of the product can cause change in physical characteristics.  
 The product should be checked for any major complications i.e. In front of spike Body clamp, flexible tubing, Injection port,  
 drip chamber, injection site, Luer lock connector, S.S Needle  
 The set so easily may increase the EO residual in the product or physical property of the products may be change.  
 Visually inspect and carefully check the product and packaging before use.  
 Improper transport and handling may cause structural/functional damage to  
 device or packaging.  
 Temperature / Humidity of the material should be done under covered. It will contain to avoid any damage, rain & direct  
 heat.

### Read instructions before use.

Prevent proper disposal of product and packing after use.  
 Use the product immediately after opening the packaging please destroy when it was used.  
 This product should be used by a Doctor / Registered Practitioner or Paramedic.

### Precautions:

Read instructions before use.  
 Check expiry date prior to use.  
 Examine before use that product / packing is not ruptured or damaged.

### Contraindications:

Product use with patients with known hypersensitivity to any of the materials used.  
 Administration of high viscous fluids.  
 Large blood transfusion.

REF Product Code

LOT Lot No./Batch No.

EC REP CMC  
C/Hispania Lengua 19-18,  
CP 29006, Málaga Spain

STERILE EO Sterilized By Ethylene Oxide

Date of Manufacturing

Use by / Expiry Date

Do Not Reuse

Do Not Re-sterilize

Non-Pyrogenic

Do Not Use if  
Package is Damaged

Latex Free

Caution

Consult Instructions For Use

Phthalate Free

Storage Condition

### M.O.H Reg. No.

REF 1.V 015

B.N 22/146

LOT 22/306

09-2022

08-2027

EC REP CMC  
C/Hispania Lengua 19-18,  
CP 29006, Málaga Spain

Euromed For Medical Industries.

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Nasr City, Cairo - Egypt

Tel. : 202 22 72 59 52/3 Fax : 202 22 72 93 74

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Website: www.euromed.com.eg



CE 1639

F/QP-25-0142/REV.01  
30/11/2021

Quality Manager  
Shimaa Rabeey

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 <p>F/OP-25-201/RW/01 30/11/2021</p>	 <p>Cautioned For Medical Industries, Area No. 108 Block B, El-Dokki, Giza, Egypt Tel: +201 2203 74000 Fax: +201 22279154 E-Mail: <a href="mailto:com@euromed.com.eg">com@euromed.com.eg</a></p>		 <p><b>Euro-Infusion Set with flash back</b> STERILE 600 PCS Made In Egypt</p>
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**Quality Manager**  
**Shimaa Rabee**

