1. Product Scope:

#	Product Name	Ref. No.	EMDN Code	GTIN
1)	Sterile Non-Vented Infusion Set Without Injection Port with Hypodermic 21G Needle with cap	IN 02	A03010103	6224008514381

2. Intended use:

I.CO IV Infusion Set is intended for the intravenous administration of fluids, electrolytes, and medications directly into the patient's vascular system.
The infusion set is used in hospitals, clinics, and emergency care environments and must be operated by trained healthcare professionals. It is strictly a single-use, sterile device intended for short-term use, typically lasting up to 4 hours per infusion session, and is not to be reused to ensure patient safety and prevent infection.

3. Instruction for Use:

- Hang infusion bottle or bag at appropriate hanger.
- Keep bottle at least 1 meter up from patient in order to create gravity force.
- Remove protective cover from solution bottle or bag aseptically.
- Remove protective cap covering insertion spike without touching the spike and insert spike into stopper of intravenous bottle or opening of intravenous bag.
- Insert infusion spike into either intravenous bottle or bag.
- Open Regulator Clamp.
- Make a fluid level in infusion chamber to 2/3 of its volume to avoid air bubble formation.
- Fill infusion tubing by compressing the drip chamber and release the chamber.
- Downstream the fluid inside infusion set to ensure there is no air inside (complete deareation) of infusion set.
- Close the clamp and just open after connection with vascular access (central or peripheral).
- Identify the best vein for inserting intravenous needle or central venous catheter and prepare according to recommended local practice.
- Connect the distal connector of the tubing set to the needle or butterfly.
- Control the clamp opening according to the desire rate of infusion.
- After finishing bottle, close the clamp and vascular access.

4. Changing intravenous solution

- Prepare to change the solution when about 50ml remains in the bottle or bag.
- Ensure the drip chamber is not less than half-full.
- Prepare the new solution. If using a plastic bag, remove the protective cover from the entry site. Do not touch the entry site on the bag or bottle.
- Move the roller clamp to stop the flow.
- Remove the old solution from the intravenous pole.
- Remove the spike from the old intravenous solution bag or bottle, and without touching the tip, insert the spike into the new intravenous solution bag or bottle.
- Hang the new bag or bottle and discard the empty bag or bottle according to hospital policy.
- Examine and expel any air in the tubing.
- Ensure the drip chamber is half-full.
- Regulate the flow to the prescribed rate

5. Removal

- Remove the needle or the plastic cannula with one hand and with the other hand cover the insertion site with sterile gauze square (2x2).
- Apply pressure for about a minute; alternatively place two pieces of narrow tape, about 1 cm or ½ inch wide, directly across the gauze square.
- Alternatively, after pressing on the gauze square, remove it and cover the insertion site with a sterile dressing.

6. Accessories

- IV stand/hanger for fluid container
- Fluid bottles or bags
- Flow regulator

7. Mode of action:

I.CO IV Infusion mode of action of the Set is based on gravity-fed infusion, whereby fluids or medications flow from an elevated container through a sterile infusion line into the patient's vascular, The gravitational force creates hydrostatic pressure that drives the fluid downward through the drip chamber and tubing, ultimately entering the bloodstream via a needle or intravenous catheter. The drip chamber allows healthcare providers to visually monitor drop formation and flow rate, helping to prevent air embolism and ensure accurate delivery.
A roller clamp or flow regulator integrated into the tubing provides fine control over the infusion rate, allowing clinicians to adjust flow according to the therapeutic requirements
System.

8. Intended patient population:

- Patients who are suffers dehydration, electrolyte imbalances, and hypovolemia.
- patients who directed by the physicians to be subjected to intravenous medication with antibiotics, chemotherapy agents, pain relievers, and parenteral nutrition solutions

The I.CO IV Infusion Set is intended for use in a wide range of patient populations requiring intravenous therapy. The device is designed for patients who need fluid replacement, electrolyte correction, or intravenous administration of medications such as antibiotics, chemotherapy, or pain management drugs .

- The I.CO IV Infusion Set is generally intended for the adult patient population with no specific limitations related to sex or body weight identified, indicating that the device may be used in both male and female patients without age or weight-based restrictions .
- The use of the I.CO IV Infusion Set in both pregnant and/or breastfeeding women is dependent on physician's decision.
- The use of the I.CO IV Infusion Set in children, infants or neonates is dependent on physician's decisions.

9. Intended user population:

The intended users of IV infusion therapy devices, including IV infusion sets, are qualified healthcare professionals such as physicians, nurses, and trained medical personnel who possess appropriate knowledge and experience in intravenous therapy, aseptic techniques, and patient monitoring. This is supported by EU MDR Annex I
requirements, which mandate clear definition of user qualifications, as well as ISO 8536-4, which assumes professional handling of infusion equipment. Additionally, risk management (ISO 14971) and usability engineering (IEC 62366-1) require that devices are designed for users with adequate training to mitigate risks such as infection, air embolism, and incorrect flow rate. Clinical guidelines from organizations such as the World Health Organization (WHO) and the Infusion Nurses Society (INS) further confirm that IV therapy must be administered by trained healthcare personnel, ensuring safe and effective use in clinical settings.

10. Contraindications

I.CO IV Infusion set and its variants are not intended to be used with patients:

- With known hypersensitivity to any of device constituent material
- Suffering from oedema

11. Precautions

Cautions before use

- Do not use if the package or if product is damaged .
- Avoid air intake and contamination .
- Check the seal of the connection made and the seal of the protection caps of the unused inlets.

Caution for storage

- Store between [5°C~30°C] avoiding exposure to direct sunlight, severe vibration and high humidity.

12. Limitations of use

Infusion set and its variant are not intended for delivery of:

- Blood or blood component
- Insulin or viscous solution

The I.CO IV Infusion Set is generally intended for the adult patient population with no specific limitations related to sex or body weight identified, indicating that the device may be used in both male and female patients without age or weight-based restrictions .
The use of the I.CO IV Infusion Set in both pregnant and/or breastfeeding women is dependent on physician's decision.
The use of the I.CO IV Infusion Set in children, infants or neonates is dependent on physician's decision.
However, the device should not be used in patients with known hypersensitivity to the device materials or in patients suffering from oedema.

13. Warnings

- Do not reuse the device, the re-use of this device may cause several infection diseases or death in case of severs infection .
- If the patient exhibits any abnormal symptoms such as discomfort, pruritus, urticaria, asthmatic hypotension reaction, hypertension and/or arrhythmia during the use of this product, take appropriate measures according to a physician's instructions .
- The expiry date refers to undamaged and properly stored product .
- Do not use for any other purposes .
- The use of the I.CO IV Infusion Set in both pregnant and/or breastfeeding women is dependent on physician's decision.
- The use of the I.CO IV Infusion Set in both children, infants or neonates is dependent on physicians' decision.

14. Shelf life/ Re-use

The I.CO IV Infusion Set is intended for single use only, with a functional lifetime limited to one continuous infusion session.
After use, it must be discarded and not reused under any circumstances to prevent risks of infection, loss of performance, or device failure. The product is supplied sterile and is designed to maintain its sterility and integrity for a shelf life of up to 5 years from the date of sterilization, provided it is stored under recommended conditions (cool, dry, shaded environment, not exceeding 30 °C, and protected from direct sunlight).

15. Packaging:
The device contained within Medical grade Paper / Ribbon pack sterilizable peel pouch, duplex box along with IFU & inner labels and outer corrugated box with identification labels.

16. Disposition:

The Disposal should comply with institutional guidelines for bio-hazardous medical waste prevailing in the country of use.

17. System Application of the body:
I.CO IV Infusion set functions as a sterile pathway connecting a fluid source (bag or bottle) to an indwelling catheter. These sets are used in various settings—from hospitals and operating rooms to home care for continuous or intermittent therapy.

18. System preparation:
- Check the label for manufactory and expiry dates (do not use the medical device after expiry)
- Check for UDI number
- Make sure the package is not damaged.
- Visually examine I.CO IV Infusion set to see if there are any damages

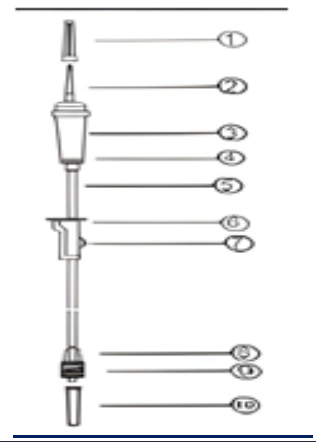
19. Guarantee

I.CO IV Infusion Set is manufactured under strict quality control and the quality is assured. If the Infusion Set is defective (broken package, damaged Infusion Set). However, it shall be replaced with a new one at our cost upon return of the broken package or damaged Infusion set. We will not be responsible, however, for the injury on a patient or any person or the damage to any object that is attributed to transport, storage and operation in your institution.

20. Cleanliness:
No cleaning is required before use. Device supplied in sterile condition and ready to use just after opening the pack.

21. Sterilization
The device is sterilized by Ethylene Oxide (EO).

22. Drawing and material composition:
product. Infusion Set is used for transferring Intravenous solutions to patient's vein.

Drawing:	SN.	Description	Material
	1.	Spike cap	Poly propylene PP
	2.	Spike	Acrylonitrile butadiene styrene ABS
	3.	Drip chamber I.V set	Poly vinyl chloride PVC
	4.	Solution filter	Poly Ethylene PE
	5.	PVC Tube	Soft PVC
	6.	Clamp body	Poly Ethylene PE
	7.	Clamp roller	Poly Ethylene PE
	8.	Flashback	Natural rubber Poly-isoprene (free latex)
	9.	Luer connector	Poly propylene
	10.	Hypodermic needle 21G with it's protective cap	Stainless steel304, PP, Dimethicone silicon oil, epoxy glue / PE

23. Label and symbol:

Symbols	Indication	Symbols	Indication
	Single use	STERILE EO	Ethylene Oxide sterilization
30°C 5°C	Storage conditions from 5°C~30°C	EU REP	EU-REP
LOT	Lot number		Single use
	Manufacturer		Consult instructions for use
	Manufacture date	LATEX	Latex free
	Expiry date		Do not use if the package is damaged
REF	Product Code		Keep away from sunlight
PHT DEHP	phthalate free		Single sterile barrier system
UDI	Unique Device Identifier	20 ml	Number of drops in millimeter
MD	Medical Device	CE 2265	CE Certificate, Notified body # 2265

24. Manufacturer information:

Manufactured / Sterilized by:	
Name	International company for Medical Necessities I.CO
Tel.	+2 088 49 50 200
Fax	+2 088 49 50 300
Factory	
Address	3rd Industrial Zone Block No. 17-20, 67 Abu-Tig, Assiut, Egypt Public Free Zone – Ismailia ,Egypt
Tel.	+2 088 49 50 200
Fax	+2 088 49 50 300
E-mail	info@medical-ico.com
Web	www.medical-ico.com
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Website	http://www.qt-int.nl/