1. **Product Name: The intravenous infusion set (IV Set)**
2. **Variants/Sizes:**

SR. No	Variant/Model	Product code	Ref. No	Group of Device Code	BASIC UDI-DI (GMN)	Class	Type of Packing	Classification Rule and Indent
1	IV Set with/without Air-vent	IVS-01	HMPLIVS01	IVS	890617438IVSSP	Class IIa	Pouch Pack Only	Rule 7 First indent

3. **Intended Purpose (Use):**
   The sterile intravenous infusion set is intended to administer fluids from a container to a patient's vascular system via a needle or catheter inserted into a vein under gravity flow. It is used for medical applications to ensure compatibility with commonly used infusion solutions

4. **Material Used:**

Direct Material		
S. No.	**Particulars**	**Description**
4.7.1	Spike	ABS
4.7.2	Spike Cover	PP
4.7.3	Drip Chamber	PVC
4.7.4	Tubing (NLT 1500 mm)	PVC
4.7.5	Roller clamp	PP
4.7.6	Latex Bulb	RUBBER
4.7.7	Roller	PP
4.7.8	Luer Connector	PP
4.7.9	Needle	SS-304
4.7.10	Needle Protector Cap	PP
Indirect Material		
4.7.11	Silicon Fluid	Lubrication
4.7.12	N-Hexane	Lubrication
4.7.13	Ethylene Oxide (20:80)	Sterilization
4.7.14	Spore Strip Biological Indicator 9372 for ETO	Sterilization Test
Packaging Material		
4.7.15	Master Pouch	Medical grade pouch Packing
4.7.16	Outer Box	3 ply outer Carton

5. **Instruction for use:**

- Firmly close the Flow regulator.
- Remove Spike cover & insert its full length into the fluid container.
- Squeeze and fill half of the drip chamber with solution.
- Remove the needle protector.
- Gently open the flow regulator to let the solution flow for displacing the entire air from tubing and needle.
- Perform vein-puncture and regulate the flow rate by opening the regulator gradually.

6. Warning:

- Do not use if package is opened or damaged.
- Single-use only. Do not reuse, reprocess, or re-sterilize.
- Contains natural rubber latex which may cause allergic reactions.
- After use, the device may pose a biohazard risk.
- Do not use if the expiry date has passed.

7. Precautions:

- Use only by trained healthcare professionals.
- Wear gloves during venepuncture to minimize exposure risk.
- Visually inspect the device prior to use.
- Do not use for blood or blood components.

8. Indication:

- Infusion of fluid such as parenteral nutrition and administration of other drugs and medicines.
- Maintaining hydration and/or correct dehydration in patients who are unable to take sufficient volume of oral fluids

9. Contra-Indication:

- Device must not be used other than as indicated in the intended purpose.
- Not intended for use in patients with known hypersensitivity to any materials used in the device.
- Not suitable for transfusion of blood or blood components.
- Not intended for infusion of highly viscous fluids that may impair flow performance.

10. Improper Use:

- The product shall not be reprocessed.
- Visually inspect and carefully check the product and packing before use.
- Improper transport and handling may cause structural and/or functional damage to device or packing.

- Hi-Tech Medics Private Limited disclaims any responsibility for possible consequences resulting from improper use.

11.Disposal of Device:

After use, dispose the device and packaging in accordance with hospital, administrative and/or local government policy.

Storage condition:

- Store in a cool, dry, and dark place at the temperature limits specified on the label. Avoid exposure to direct sunlight. Exceeding the maximum recommended storage temperature may lead to impairment of the IV Set quality.

NOTE TO USERS: Any serious adverse event occurring in relation to the device in question should be reported to the manufacturer (mentioned on the labels) and the competent local authority.

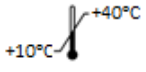
12.Shelf life of device:

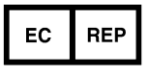
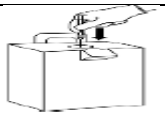
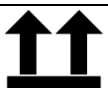
The shelf life of the device is clearly indicated on the product label.

Users shall always refer to the expiry date mentioned on the individual device label prior to use.

Note: In case of any ambiguity in the translated language version's interpretation, the original English language text shall be the authoritative/Reference text. This device is a medical device in accordance with Regulation (EU) 2017/745.

Descriptions of symbols as per ISO 15223-1: 2021:

S. No.	Descriptions	Symbols	S. No.	Descriptions	Symbol
1.	Caution / Warning (Read IFU before use)		2.	Moisture Limitation	
3.	Product reference / Artwork No.		4.	Temperature Limitation	
5.	Do Not Reuse		6.	Do not use if package is damaged	
7.	Lot No. / Batch No.		8.	Consult for IFU	

9.	Date of Manufacturing		10.	CE Marking	
11.	Used by/ Expiry Date		12.	Keep Away from Sunlight	
13.	Sterilized by Ethylene oxide		14.	European authorized Representative	
15.	Manufactured by		16.	Do not Re-sterilize	
17.	Keep Dry		18.	Non-Pyrogenic	
19.	Fragile, Handle with Care		20.	Safe Disposal of IV Set	
21.	Unique Device Identifier		22.	Single sterile barrier system	
23.	Medical device		24.	Store and stack in upright condition	
25.	Contain Latex		26.		

	Name	Designation	Signature	Date
Prepared By	Mr. Ashad Ahmad	Sr. Executive	Ashad Ahmad	10.01.2026
Reviewed By	Mr. Atiquer Rahman	GM - Production		10.01.2026
Approved By	Mr. Rahul Kumar	Quality Head & MR		10.01.2026