POLY MEDICURE LIMITED

TECHNICAL DATA SHEET
Infusion Set

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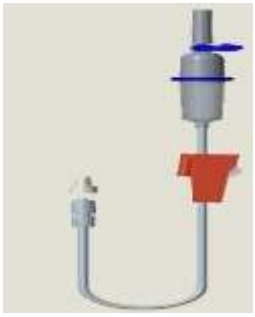
Product Codes	Product Description
14001-14029,14050-14054, 14074-14075,14079-14081, 14083-14089, 14159, 14210-14219	IV Infusion Set with Vented spike
14030-14044, 14055-14059, ,14189-14190, 14200	IV Infusion Set with Non-vented spike
14082, 14090-14116	IV Infusion Set with Flow Regulator
14280-14282	Micro IV Infusion Set with vented spike
14120-14139,14153, 14157-14158,14165-14168,14174, 14370-14377, 14380-14383	IV Infusion Set with Vented
14140-14149,14154,	IV Infusion Set with Non-vented
14230-14233,14235	Photo Fusion IV Infusion Set with vented spike
14160-14164, 14169-14172	Intravenous Fluid Infusion Set with 0.2 µm Filter
14260-14264,14268-14269,14279,14289-14297	Intravenous Fluid Infusion Sets with Auto air stop and Priming Filter
14150	IV Infusion Set with Non-Vented wing spike
14155-14156	IV Infusion Set with Vented wing spike
14265-14267	Auto stop IV Infusion Set with vented spike
14060-14068,14070, 14073	Micro IV Infusion Set with Non-vented
14069, 14071-14072	Micro IV Infusion Set with Vented
14270-14272	Intravenous Fluid Infusion Sets with Three way Stop cock and Priming filter
14170-14171, 14177	IV Infusion Set with Vented spike, with 0.2 µm Filter & PVC free
14180-14183,	IV Infusion Set with Vented spike & Double Needle free Y-site
14401-14414	IV Set vented with wings
14275	IV Infusion Set with vented spike
14784-14799	PVC Free Infusion Set
14800-14811, 14824-14826, 14830-14844	Non-vented Infusion Set with BCV, 2 Needle free Y- Syte
14812-14823, 14827-14829,14845-14859	Vented Infusion Set with BCV, 2 Needle free Y- Syte
14870-14881,14894-14896,14960-14974	PVC Free Non-vented Infusion Set with BCV, 2 Needle free Y- Syte
14882-14893,14897-14899,14975-14989	PVC free Vented Infusion Set with BCV, 2 Needle free Y- Syte

Product Image

		
Polyfusion Vented Set	Microfusion Set	Polytrol Set

		
Novofusion Set	Oncofusion Set	Neofusion Set
		
Polyfusion-W Set	Polyfusion Set	Photo fusion Set
		
Polyfusion vented set with Three Way stop cock	Autofusion Set	

General Information:

Intended Use

The Infusion Set is used for gravity feed or pressure infusion to administer intravenous fluid and medicines into human circulating system by using intravenous catheter or cannula.

Legal Manufacturer-
POLY MEDICURE LIMITED
Plot No.: 104-105, Sector 59, HSIIDC Industrial Area, Ballabhgarh,
Faridabad -121004, HARYANA, INDIA

Plot No.:115, 116 & 117, Sector 59, HSIIDC Industrial Area, Ballabhgarh, Faridabad, Haryana, INDIA – 121004

Plot No.: 33-34, Sector 68, IMT,

Faridabad- 121004, Haryana, INDIA

Plot No. PA-010-018, PA-010-019, Mahindra World City (Jaipur) Ltd., Multi-Product SEZ, Jaipur, Rajasthan 302037, INDIA

Plot No. 17, Sector-3, Integrated Industrial Estate, SIDCUL Haridwar, Uttarakhand 249403, INDIA

Manufacturing Site:
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European Authorized Representative- Name and address
OBELIS S.A.
Boulevard Général Wahis 53,
B-1030, Brussels,
Belgium

Certification:

Manufacturing Site	Certification	Notified Body
POLY MEDICURE LIMITED *Plot No.:104-105, Sector 59, HSIIDC Industrial Area, Ballabhgarh, Faridabad, Haryana, INDIA – 121004*	*CE Certificate* *Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III* ***CE Certificate No.: G10 041938 0011***	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany **Notified Body Number: 0123**
	EN ISO 13485:2016/DIN-EN ISO 13485:2016 ***Certificate No.: Q5 041938 0001***	
Plot No.:115, 116 & 117, Sector 59, HSIIDC Industrial Area, Ballabhgarh, Faridabad, Haryana, INDIA – 121004	*CE Certificate* *Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III* ***CE Certificate No.: G10 105484 0003***	
	EN ISO 13485:2016/DIN-EN ISO 13485:2016 ***Certificate No.: Q5 041938 0001***	
POLY MEDICURE LIMITED	*CE Certificate*	

Manufacturing Site	Certification	Notified Body
Plot No.: 33-34, Sector 68, IMT, Faridabad- 121004, Haryana, INDIA	*Medical Device Directives 93/42/EEC- Annex II* ***CE Certificate No.: G1 105485 0007 (CL 105485 0010)***	
	EN ISO 13485:2016/DIN-EN ISO 13485:2016 ***Certificate No.: Q5 105485 0006***	
POLY MEDICURE LIMITED Plot No. PA-010-018, PA-010-019, Mahindra World City (Jaipur) Ltd., Multi-Product SEZ, Jaipur, Rajasthan 302037, INDIA	*CE Certificate Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A* ***CE Certificate No.: G20 105735 0009***	
	EN ISO 13485:2016/DIN-EN ISO 13485:2016 ***Certificate No.: Q6 105735 0006***	
Plot No. 17, Sector-3, Integrated Industrial Estate, SIDCUL Haridwar, Uttarakhand 249403, INDIA	*CE Certificate Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A* ***Certificate No.: G20 105486 0001***	
	EN ISO 13485:2016/DIN-EN ISO 13485:2016 ***Certificate No.: Q5 041938 0001***	

Device Classification:

- As per the "Classification criteria" *Annexure- VIII of the Regulation (EU) 2017/745*, the Infusion set is used for more than 60 minutes and less than 30 days. Hence this device is for 'short term use' as per the description in the *1.2 of Annexure- VIII*.
- The needle of IV Infusion Set penetrates inside the surface of body, hence is "Invasive device" *as per 2.2 of Annexure- VIII.* As per the Regulation, devices which penetrates the body through other than an established body orifice is Surgically Invasive Devices hence IV Infusion Set is "Surgically Invasive Device".
- As per Rule 7 for Classification, all surgically invasive devices intended for short-term use are in Class IIa. Hence IV Infusion sets are classified as Class IIa Medical device.

Device Description:

An Intravenous fluid infusion set is a sterile, Non - Toxic & Non-pyrogenic product used for infusion of fluid such as parenteral nutrition and administration of other drugs or medicines into human circulating system by using intravenous catheter or cannula. The IV set is designed to maintain hydration and/or correct dehydration in patients who are unable to take sufficient volume of oral fluids through gravity as well as pressure infusion method. The intravenous route of administration can be used for injections (with a syringe at higher pressures) or infusions. The intravenous route is the fastest way to deliver medications and fluid replacement throughout the body, because the circulation carries them. Intravenous therapy may be used for fluid replacement (such as correcting dehydration), to correct electrolyte imbalances, to deliver medications, and for blood transfusions.

The IV fluids are administered through thin, flexible plastic tubing called an infusion / administration set. The infusion tubing/administration set connects to the bag of IV solution. Medications may be mixed into the fluids.

Compared with other routes of administration, such as oral medications, the intravenous route is the fastest way to deliver fluids and medications throughout the body.

Technical Specification:

An Intravenous fluid infusion set may include the drip chamber, fluid delivery tubing and connectors between parts of the set and a hollow spike to connect the tubing to an IV bag or medication bag/bottle, Three way stop cock, Back check valve, Needle free connectors etc. IV tubing is either a macro-drip solution administration set that delivers 20 drops/ml, or a micro-drip set that delivers 60 drops/ml. Macro-drip sets are used for routine primary infusions. Micro-drip IV tubing is used mostly in pediatric or neonatal care, when small amounts of fluids are to be administered over a long period of time.

Based on the application and requirements, various features are incorporated in the product designs as follows:

Intravenous Fluid Infusion Sets with/without Air vent/with Flow regulator/with three way stop cock

- Sharp and easy piercing air vented spike empties without residue.
- Bacteria retentive air inlet with snap on cap.
- 15-micron fluid filter in drip chamber aids in reduction of particulate matter
- Clear, flexible & transparent drip chamber and also available with small, medium & long drip chamber.
- Approximately 20 drops equal to 1±0.1ml of distilled water
- The product is available in DEHP free tubing. Kink resistant PVC tubing.
- Product is provided with flow controller to control the rate of flow with range of 5 to 250 ml/hr, pressure up to 4.5 bars (65 psi).
- Molded latex flush bulb made of Polyisoprene using for intermittent medication.
- Tube length is available in 150cms, 180cms & 200cms DEHP free. Available with Male luer at one end and Female luer at other ends.
- Flow regulator integrated into IV infusion set for precise flow control.

Micro Drip Intravenous Fluid Infusion Sets with and without Flow regulator

- Micro IV Infusion set for Pediatric use only
- Approximately 60 drops/ml

Intravenous Fluid Infusion Set with Filter

- I.V. Infusion set with 0.2-micron IV in-line filter in order to prevent any particles, entrapped air and bacteria & fungi passing into the venous system.
- The product is available in DEHP free tubing.

Infusion Set with Auto Air Stop Filter

- Prevent the entry of air in the line when the I.V. bottle is empty.
- Auto Air Stop Filter maintains a constant fluid level and reduces the possibility of air in the I.V. Line.

Intravenous Fluid Infusion Set with Double needle free y-site

- Sharp and easy piercing air vent spike empties without residue.
- Two needle free y-site which combined with both luer lock or luer slip syringes.
- The product is available in DEHP free tubing.
- Priming volume of needle free y-site is 0.19ml.

Infusion Set with Priming Filter.

- *The special Priming Filter ensures that the line fills automatically (Auto Prime) thus maintains a closed system.*
- *Helps in reducing Healthcare Associated infections (HAI)*
- *Reduces spillage and wastage of I.V. fluid.*

Infusion Set for Photosensitive Drugs.

- *Protects light sensitive drugs from UV exposure.*
- *UV resistant tubing minimizes decomposition of the active ingredients of various drugs.*
- *Hydrophobic priming filter cap to prevent fluid leakage.*
- *The product is available in DEHP free tubing.*

Infusion set with Winged Spike

- *Sharp and Winged spike for easy insertion.*

The product is sterilized using EO (Ethylene Oxide) gas and the packaging doesn't contain any constituent of animal origin.

Inner & Outer diameter of Tube:

Tube Dimension	
Outer Diameter (OD)	4.05±0.1 mm
Inner Diameter (ID)	2.85±0.1 mm

Approved Materials of Constructions:

S. No.	Part where material is used	Base Material	CAS Number
1.	Spike Cover	Polypropylene	9003-07-0
2.	Air Vent filter	Acrylic Copolymer Membrane	25133-97-5
3.	Screw cap	Polycarbonate	25037-45-0
		ABS	9003-56-9
4.	Air vented spike	Acrylonitrile Butadiene Styrene	9003-56-9
5.	Non - vented spike	Acrylonitrile Butadiene Styrene	9003-56-9
6.	Hard Spike	GPPS/ABS	9003-55-8
7.	Micro Dripper Body	ABS	9003-56-9
8.	Air Closure Cap / Air Vent Cap	LDPE+HDPE	9002–88–4+9002–88–4
		PVC (DEHP Free)	9002-86-2
		Polypropylene	9003-07-0
9.	Roller body	Polypropylene	9003-07-0
		Acrylonitrile Butadiene Styrene	9003-56-9
10.	Roller wheel	Polypropylene	9003-07-0
		ABS	9003-56-9
11.	Drip chamber	PVC compound	9002-86-2
	PVC free Drip Chamber	TPE	308079-71-2
	Drip chamber 2	TPE	308079-71-2
		Styrene Butadiene Copolymer	9003-55-8
12.	Joint Ring Assembly	Styrene Butadiene Copolymer	9003-55-8
13.	PE CAP /LD Cap	LDPE	9002–88–4

S. No.	Part where material is used	Base Material	CAS Number
14.	Jimny Filter	Polypropylene	9003-07-0
		Acrylic Copolymer Membrane	25133-97-5
15.	Purge Filter cap	HDPE	9002–88–4
16.	Latex Bulb	Natural Rubber	N/A
17.	Y-site	ABS	9003-56-9
	Latex	Natural Rubber	N/A
18.	Y-site (Needle Free)	Polycarbonate + Silicon	103598-77-2 + 7440-21-3
19.	Rotating Luer lock (Body)	RPVC	9002-86-2/9003-56-9
		Acrylonitrile Butadiene Styrene	
20.	Male Luer Lock (Fixed)	RPVC	9002-86-2
		ABS	9003-56-9
21.	Male Luer Lock cap	HDPE	9002–88–4
22.	Adopter	Polypropylene	9003-07-0
		RPVC/ABS	9002-86-2/9003-56-9
23.	Tubing	PVC compound	9002-86-2
24.	PVC free Tubing	TPE	308079-71-2
25.	Needle	Stainless Steel	65997-19-5
26.	Needle Hub	Poly Propylene	9003-07-0
27.	Needle Cover	Poly Propylene	9003-07-0
28.	Disc Filter	ABS	9003-56-9
29.	Blue Disc	ABS	9003-56-9
30.	Hydrophilic Filter	Hydrophilic Paper	N/A
31.	0.2 Micron inline filter	ABS/Filter	9003-56-9/N/A
32.	Big Tube Clamp	Poly Propylene	9003-07-0
33.	C-Clamp	Poly Propylene	9003-07-0
34.	Autofly Connector	ABS	9003-56-9
35.	Channel Housing	Polycarbonate	25037-45-0
36.	Handle	HDPE	9002–88–4
37.	Flow Regulator	ABS	9003-56-9
		TPR/TPE	308079-71-2

Sterilization Method:

Sterilized using Ethylene Oxide

Shelf Life:

Five years from the date of manufacturing.

Standards Compliance:

Sr. No.	Document Code	Document Description
1.	EN ISO 13485:2016+ A11:2021	Quality system - Medical Devices - Requirements for the Regulatory Purposes

Sr. No.	Document Code	Document Description
2.	*EU MDR 2017/745*	*European Medical Devices Regulation*
3.	EN ISO 14971:2019*/ A11:2021*	Application of risk management to medical devices
4.	*IEC 62366-1:2015/Amd 1:2020*	Medical devices — Part 1: Application of usability engineering to medical devices — Amendment 1
5.	EN ISO 15223-1*:2021*	Symbols to be used with medical devices labels, labeling and information to be supplies
6.	*ISO 20417:2021*	*Medical devices — Information to be supplied by the manufacturer*
7.	EN ISO 11135:2014*/ A1:2019*	Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices
8.	EN ISO 11607-1:*2020/A11:2022*	Packaging for terminally sterilized medical devices – requirements for materials, sterile barrier & packaging systems.
9.	EN ISO 11607-2:*2020/A11:2022*	Packaging for terminally sterilized medical devices – Validation requirements for forming, sealing and assembly process.
10.	*ISO 11737-1:2018/ Amd 1:2021*	*Sterilization of health care products -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products.*
11.	*EN ISO 11737-2:2020*	*Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.*
12.	EN ISO 10993-1:*2020*	Biological evaluation of medical devices – Evaluation and testing within a risk management process.
13.	ISO 10993-7:2008 */ A1:2022*	Biological evaluation of medical devices – Ethylene oxide sterilization residuals
14.	*EN ISO 8536-4:2019*	Infusion Sets for Single Use - Gravity feed only
15.	*EN ISO 8536-8:2015*	Infusion equipment for medical use -- Part 8: Infusion sets for single use with pressure infusion apparatus
16.	*EN ISO 80369-7:2021*	Small-bore connectors for liquids and gases in healthcare applications -- Part 7: Connectors for intravascular or hypodermic applications.
17.	*EN* ISO 14644-1:2015	Clean rooms and associated controlled environments – Classification of air cleanliness

Reference to Internal Quality Documents:

Document Title	Polymed Internal Document Reference
Technical File	PML/MD/TF/1.03
Product Specification	FP/QA/06
Risk Management	PML/MD/RA/1.03
Clinical Evaluation	PML/MD/CER/03
DOC	F/QA/176

Packaging Characteristics:

The Infusion Sets are packed in soft blister and / or Ribbon Pouches as per requirement. Unit package bottom shall be a soft blister formed of PP+PE film, which should be clear, and this shall be sealed with a printed lid of medical grade, non-toxic lacquered paper. Unit package shall maintain a sterility barrier through its seal. The integrity of the package shall not be compromised during normal handling, storage, sterilization, or transportation. Unit package shall open reliably without tearing and particulate matter generation.

Twenty-five (25) pcs of unit packages shall be packed into one Inner Duplex printed cardboard box. Twenty (20) Duplex boxes shall be packed into one corrugated shipper box, as per customer requirement. The combination of shipper box/duplex box/unit packaging system shall provide adequate product protection during normal shipping, handling, and storage, till the product reaches the end user.

Storage Conditions:

Store in between 5°C to 35°C, avoid excessive heat, protect from direct sunlight and moisture.

Materials of Concern:

- *Not made with DEHP plasticizer.*
- Any substances of animal origin e.g. BSE/TSE are not used during manufacturing.