

Technical Information Data Sheet

Description: Pump set

Code: MT-1100

Class: II a

UMDNS-Code: 16579

Sterilization Way: Can be EO Sterilized

Destination/use: For single use

DEHP Free: Yes

Latex Free: Yes

Biocompatibility: Yes

Non-pyrogenic: Yes

Conformity: European Directive 93/42/EEC

Standards:

The applicable harmonized standards:

ISO 8536-4: Infusion equipment for medical use- part 4: infusion set

ISO 8536-8: Infusion Equipment for medical use- Part 8: Infusion sets for single use with pressure infusion apparatus

ISO 594-1:Conical Fittings with a 6% (Luer) Taper for Syringes, Needles and certain other Medical Equipment – Part 1: General Requirements

ISO 594-2:Conical Fittings with a 6% (Luer) Taper for Syringes, Needles and certain other Medical Equipment – Part 2: Lock Fittings

ISO14971: Medical Devices- Application of risk management to medical device

ISO13485: Medical Devices- Quality management systems – Requirements for regulatory purposes

Shelf life: 3 years

Technical Characters:

1. Available in Needle-Free, Pre-Pierced and Injection Y-sites in an array of sets to meet your clinical needs;
2. Tube is made by DEHP free PVC.
3. Tensile strength > 15N/15S.
4. It can hold 275kpa/15min for water pressure and 275kpa/3s for air pressure.

Composition and package information:

	Part	Color	Material
Composition	Spike	-	PE, DEHP FREE PVC, 0.5um Glass Fiber,ABS
	Tube 1220*4.75*6.6mm	Natural	DEHP FREE PVC
	Connectors CN26-6.6	White	ABS
	Clip KK01	Natural	POM
	Pump Tube 210*3*7mm	Natural	Silicone
	Connectors CN26-4.0	White	ABS
	Tube 1530*2.9*4.05mm	Natural	DEHP FREE PVC
	House MH01	White	ABS
	Male Luer Lock MLL04-4.0	Natural	PC

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	Cap HT107	Natural	PE
Quantity	1pcs/paper pouch (Tyvek) ,10pcs/box,100pcs/case		
Carton size	460*430*570mm	Gross weight	8.2 kg
Photo			

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