

Technical Information Data Sheet

Description: Luer Connector

Product code: MT-3915

Class: IIa

UMDNS-Code: 11729

Sterilization Way: Can be EO Sterilized

Destination/use: For single use

DEHP Free: Yes

Biocompatibility: Yes

Non-pyrogenic: Yes

Conformity: European Directive 93/42/EEC

Standards:

The applicable harmonized standards:

EN ISO 8536-4:2019 Infusion equipment for medical use- Part 4: Infusion sets for single use, gravity feed

EN ISO 8536-8:2015 Infusion equipment for medical use- Part 8: Infusion sets for single use with pressure infusion apparatus

EN ISO 594-2 Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment —Part 2:Lock fittings

EN ISO14971:2016 Medical Devices- Application of risk management to medical device

EN ISO13485:2016 Medical Devices- Quality management systems – Requirements for regulatory purposes

ISO 11607-1 Packing for terminally sterilized medical device- Part 1: Requirements for materials sterile barrier systems and packaging systems.

ISO11607-2 Packing for terminally sterilized medical device- Part 2: Validation for requirements for forming, sealing and assembly processes.

Shelf life: 3 years

Technical Characters:

1. Free of air or liquid leakage under liquid pressure 300kPa to 330kPa over a period 30s to 35s.
2. Resistance to overriding.
3. Resistance to easy loose once the luer locked.

Composition and package information:

Composition	Part	Color	Material
	Luer Connector MT-3915	Red	PP
Cap HT152	White	PE	
Quantity	1pcs/paper pouch,100pcs/bag,1000pcs/case		
Carton size	680*380*180mm	Gross weight	3.9 kg
Photo			

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APPROVED

Mik
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