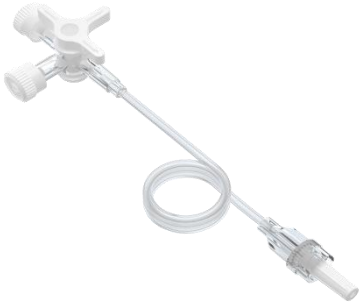


1. PRODUCT DESCRIPTION:

Three-way Stopcock with extension tube: Three way stop cock with an integrated extension tube consists of 2 female Luer ports and a male Luer lock. All the three ports are capped. The product is made from PP, PC, and PVC & HDPE material. Generally the tap is in white color but if needed it can be made in blue or red colour for indicating venous or arterial use. It is used for minimizing the manipulation during intravenous administration of fluids/drugs through an intravenous catheter. Duration of Use: Short term.

2. DEVICE CLASSIFICATION AND RULE:

The device is classified as Class IIa/Rule 2, medical device (classification as per MDR Annex II Section 1.1(f); Annex VIII)

3. PRODUCT CHARACTERISTICS & INTENDED USE:

Lipid Resistant 3-way Stop cock with Extension Tube: Three Way Stop cock with Extension tube is used with infusion or transfusion set which permit for connection with any medical equipment, in order to improve the ease of use. It also provides an alternative channel for the introduction of medication to the patient. It can withstand contact with lipids (such as fats and oils).

It has a two-fold function:

- To serve as a protective stopper for any standard "female luer"
- To provide two additional ports for administration of any fluid. This device can be lipid resistant/can be non-lipid resistant.
- To serve as an extension line to the product being used in infusion therapy.
- Arrows marks on tap indicate direction of flow
- Transparent (free from blue tinge) for better flow and visualization

4. PRODUCT VARIANTS:

Following variants are available for the products:

S. No.	Product	Size	Basic UDI-DI	Colour	Type	GMDN Code	Classification / Rule
1.	3 Way Stop Cock with Extension tube **(Lipid resistant)**	Blue, Red, White & 45 degree click.	++G4013ELMR	White	Lipid resistant	32172	Class-IIa, Rule-2

5. MATERIAL OF CONSTRUCTION:

Three way stop cock with extension tube		
S. No.	**Component Description**	**Material used**
1.	3-way body with Ext. tube	P.C. (Polycarbonate)
2.	Threaded Stopper	H.D.P.E.(High-density polyethylene)
3.	Three way tap	H.D.P.E.(High-density polyethylene) + L.D.P.E.(High-density polyethylene)
4.	Plain stopper	P.P. (Polypropylene)
5.	Extension Tube	PVC (Polyvinyl chloride)
6.	Male Luer Lock	P.C. (Polycarbonate)

6. PRODUCT SPECIFICATION:

Three way stop cock with extension tube				
S. No.	**Characteristics**	**Specified**		**Tolerance**
1.	Flow Rate	450 ml/min		± 10%
2.	Air Leakage Test	No leakage at 3 bar pressure		-
3.	Liquid Leakage Test	No leakage at 3 bar pressure		-
4.	Total Height of Assembled pcs	20.00 mm		± 0.1mm
5.	Leakage Rate in Pascal	≤0.005 PA.m^3 /S		-
6.	Tap Rotation Test	should be jerk free		-
7.	Packaging Integrity Test	Test pass at 200 mm of Hg		-
8.	Color of Tap	Blue/white/red		-
9.	Sealing Strength (force in Newton)	for soft blister	6	± 2
		Rigid PVC with 60 gsm	≥1.5N	-
		Rigid PVC with Tyvek	≥1.5N	-
10.	Effective Tube Length	7 cm		± 5%
11.	Tube OD	3.8 mm		± 0.05 mm
12.	Tube ID	2.8 mm		± 0.05 mm
13.	Filling Volume	0.8ml		-

7. REFERENCE COMPLIANCE STANDARD:

S. No.	Name of Standard	Number
Threeway Stop cock with Extension Tube		
1.	Infusion equipment for medical use Part 10: Accessories for fluid lines for single use with pressure infusion equipment	ISO 8536-10:2015
2.	Small-bore connectors for liquids and gases in healthcare applications Part 7: Connectors for intravascular or hypodermic applications	ISO 80369-7:2021

3.	Infusion equipment for medical use Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact	ISO 8536-14:2016
General		
4.	Sampling procedures for inspection by attributes Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	ISO 2859-1 : 1999
5.	Clean Rooms And Associated Controlled Environments: Classification of air cleanliness by particle concentration	EN ISO 14644-1:2015
6.	Clean Rooms And Associated Controlled Environments : Monitoring to provide evidence of clean room performance related to air cleanliness by particle concentration	EN ISO 14644-2:2015
7.	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements	EN ISO 15223-1:2021
8.	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices	EN ISO 11135:2014
9.	Sterilization of health care products - Biological indicators - Part 1: General requirements	EN ISO 11138-1:2017
10.	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products	EN ISO 11737-1:2018
11.	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems	EN ISO 11607-1:2019
12.	Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes	EN ISO 11607-2:2019
13.	Biological evaluation of medical devices –part 1, Evaluation and testing within a risk management process	EN ISO 10993-1: 2018
14.	Biological evaluation of medical devices — Part 3: Tests for Genotoxicity, carcinogenicity and reproductive toxicity	EN ISO 10993-3:2014
15.	Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood	EN ISO 10993-4:2009
16.	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	EN ISO 10993-5:2009
17.	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals	EN ISO 10993-7:2008
18.	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	EN ISO 10993-10:2021
19.	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	EN ISO 10993-11:2017
20.	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	EN ISO 10993-12:2021
21.	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances	EN ISO 10993-17:2023
22.	Clean rooms and associated controlled environments- bio-contamination control- general principles and methods	EN ISO 14698-1:2003
23.	Clean rooms and associated controlled environments- bio-	EN ISO 14698-2:2003

	contamination control- evaluation and interpretation of bio-contamination	
24.	Medical devices -- Quality management systems -- Requirements for regulatory purposes	ISO 13485:2016
25.	Medical devices – application of risk management to medical devices	EN ISO 14971:2019
26.	European council directive concerning medical devices	MDR 2017/745

8. PACKAGING DETAILS:

S. NO.	Type of Packaging	No. of Pieces (10cm to 100cm	No. of Pieces (150cm to 250cm
1.	Blister Pack	01	01
2.	Inner (Duplex) Box	50	30
3.	Outer/Master Carton (Corrugated box)	500	300

9. COMPLIANCE INFORMATION:

Manufacturer Information: Disposafe Health and Life Care Ltd., Plot No. 1 & 2, Phase-II, Sec-59, Ballabgarh, Faridabad-121004, Haryana (INDIA)
Drug Manufacturing License No.: MFG/MD/2019/000106
QMS Certification: EN ISO 13485:2016, TUV SUD Product Service GmbH CE Marking: **TUV SUD Product Service**: GmbH, EC Notified body No. 0123 GMDN Code: 32172

10. ABBREVIATIONS:

QMS – Quality Management System
GMDN – Global Medical Device Nomenclature
PP – Polypropylene
PC – Polycarbonate
H.D.P.E – High-density polyethylene
L.D.P.E – Low-density polyethylene
3 WSC – Three way Stopcock