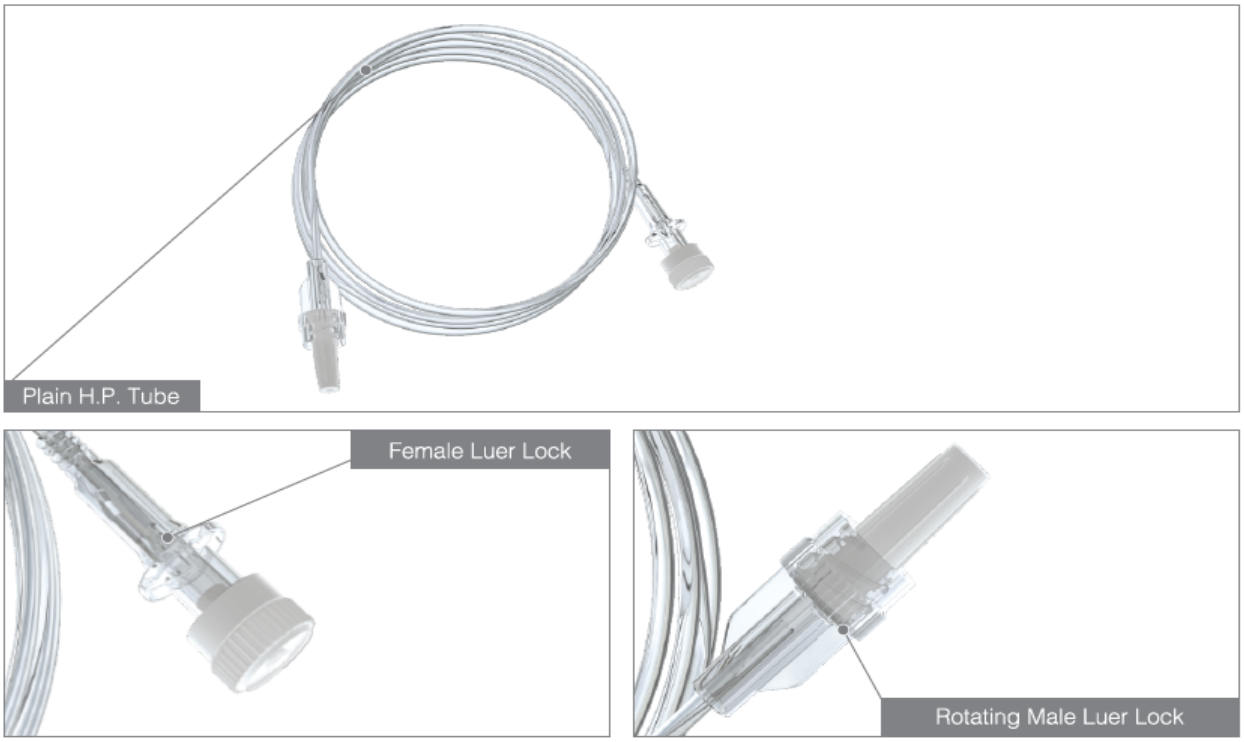


1. PRODUCT DESCRIPTION

Pressure monitoring line is used for observing the pressure through extended medical soft, kink resistant PVC tubing which ensures smooth fluid movement. Duration of Use: Short term. Material of Composition: PVC, HDPE, PP.

2. DEVICE CLASSIFICATION AND RULE

The device is classified as Class IIa/Rule 2, medical device as per EU MDR 2017/745 Annexure VIII.

3. INTENDED USE

Pressure monitoring line is intended for continuous measurement of blood pressure or other physiological pressure of a bed bound patient.

4. PRODUCT FEATURES

SMALL BORE HIGH PRESSURE EXTENSION LINE:

- It is suitable for Pressure Monitoring
- It has small bore for High Pressure (Upto 140psi)
- Made of P.V.C
- Leak proof male Luer lock and female luer lock made according ISO 80369-7 are provided at ends ensure, fitment to all standard medical Equipment and Devices.

AVAILABLE IN FOLLOWING CONFIGURATION:

- Length: 50, 100, 150, 200, 250cm

- Tube Diameter: Internal 1.2 mm & external 2.8 mm
- Colour coded sticker provided for identification of connection.
- Packed is peel open pouch or soft blister pack.
- Capacity 1.0 ml per 100cm
- Male luer at one end Female luer at other end.
- Male luer & female luer complies ISO-803639-7.
- Sterile/Non-Pyrogenic/Single use.

OPTION AVAILABLE: DEHP Free PVC Tube/Lipid Resistant/Tube Length 10cm to 250cm/Minimum Priming volume.

5. PRODUCT VARIANTS

S.no.	Variant	Article No.
1.	PRESSURE MONITORING LINE with Male & Female Luer	PML-1
2.	PRESSURE MONITORING LINE with Female & Female Luer	PML-2
3.	PRESSURE MONITORING LINE with Male & Male Luer	PML-3

6. MATERIAL OF CONSTRUCTION

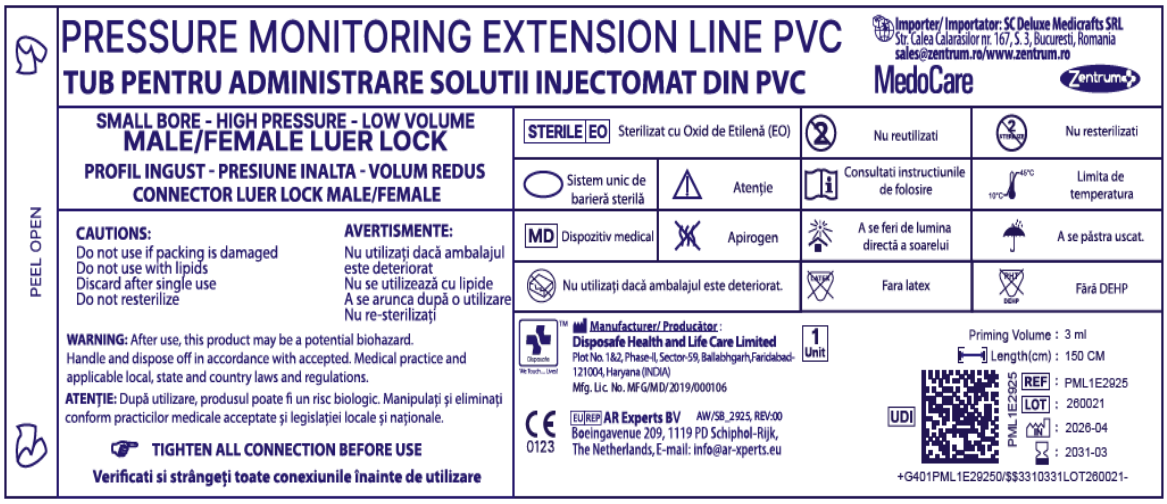
S. No.	Component/Parts	Material used
1.	Plain Stopper	PP (Polypropylene)
2.	Male Luer Lock	PC (Poly Carbonate)
3.	Tube	PVC (Poly-vinyl Chloride)
4.	Female Luer Lock	PC (Poly Carbonate)
5.	Threaded Stopper	HDPE (High Density Polyethylene)

7. PRODUCT SPECIFICATION

S. No.	Size	Ext.-int. Dia (mm)	Length
1.	150	2.8/1.2	150
2.	200	2.8/1.2	200
3.	250	2.8/1.2	250

8. PACKAGING DETAILS AND SPECIFICATIONS

ITEM	TYPE OF PACKAGING	PACKAGING
Primary Packing	Soft Blister Packaging	01
Inner Carton	3 PLY Corrugation White Box	50
Master Carton	5 PLY Corrugation White Box	500



Soft Blister Artwork PM Line

9. REFERENCE COMPLIANCE STANDARD

S.No.	Name of Standard	ISO Std. No.
Standard for Pressure Monitoring Line		
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 health care applications	EN ISO 80369-7:2021
3.	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/Amd 1:2011
4.	Clean Rooms And Associated Controlled Environments: Classification of air cleanliness by particle concentration	EN ISO 14644-1:2015
5.	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
6.	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
7.	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices	ISO 11135:2014/Amd 1:2018
8.	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	ISO 11607-1:2019/Amd 1:2023
9.	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	ISO 11607-2:2019/Amd 1:2023

Prepared by:	Reviewed by:	Approved by:	Issued by:	
Name: Harpreet Kaur Desig.: Executive, QA	Name: Hardik Bhan Desig.: Manager, QA	Name: Krishanu Bose Desig.: General Manager	Name: Hardik Bhan Desig.: MR	DISPOSAFE HEALTH AND LIFE CARE LTD.

10.	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1:2020
11.	Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood	EN ISO 10993-4:2017
12.	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	EN ISO 10993-5:2009
13.	Biological evaluation of medical devices — Part 6: Tests for local effects after implantation	EN ISO 10993-6:2016
14.	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals	ISO 10993-7:2008/Amd 1:2019
15.	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	EN ISO 10993-10:2021
16.	Biological evaluation of medical devices - Part 11 : Tests for systemic toxicity	EN ISO 10993-11:2018
17.	Biological evaluation of medical devices - Part 12 : Sample preparation and reference materials	ISO 10993-12:2021
18.	Biological evaluation of medical devices- Part 17 : Establishment of allowable limits for leachable substances	EN ISO 10993-17:2023
19.	Medical devices -- Quality management systems -- Requirements for regulatory purposes	EN ISO 13485:2016
20.	Medical devices – application of risk management to medical devices	EN ISO 14971:2019
21.	Clean rooms and associated controlled environments- bio-contamination control- general principles and methods	EN ISO 14698-1:2003
22.	Clean rooms and associated controlled environments- bio-contamination control- evaluation and interpretation of bio-contamination	EN ISO 14698-2:2003
23.	Medical devices - Part - 1: Applications of Usability engineering to the medical devices.	IEC 62366: 2015
24.	Sterilization of health care products- Microbiological methods- Part 1: Determination of a population of microorganisms on products	EN ISO 11737-1:2018
25.	Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)	EN ISO 11737-2:2020

10. OTHER DETAILS

10.1. **Intended Use:** refer the instruction for use before the application.

10.2. **Storage:** store in a cool and dry place and keep away from direct sunlight and extreme heat.

10.3. **Method of Sterilization:** sterilized using ethylene oxide.

10.4. **Shelf life:** 05 years from the month / date of sterilization.

10.5. **Testing and Analysis:** Testing for sterility, pyrogen content and physical characteristics (leakage testing, packaging integrity, etc.) is performed on each batch before release.

10.6. **Biocompatibility:** the product is tested as per the international standard ISO 10993-1 and parts applicable, and evaluation results are found conform to the standard requirements. The report from the actual study is available with Quality Assurance and will be available for review on request.

10.7. **Disposal:** Dispose of the used product in to biohazard container / clinical wastage bag or according to hospital and country specific protocol.

11. COMPLIANCE INFORMATION

Manufacturer Information: Disposafe Health and Life Care Ltd., Plot No. 1 & 2, Sec-59, Phase-II,Ballabhgarh, Faridabad-121004, Haryana (INDIA)
Drug Manufacturing License No.: MFG/MD/2019/000106
QMS Certification: EN ISO 13485:2016**,** TUV SUD Product Service GmbH
CEMarking: TUV SUD Product Service GmbH, EC Notified body No. 0123
GMDN Code: 35529

12. ABBREVIATIONS

QMS – Quality Management System
GMDN – Global Medical Device Nomenclature