POLY MEDICURE LIMITED

TECHNICAL DATA SHEET

Abdominal Drainage Set

Digitally signed by Iarovoi Petru
Date: 2025.05.31 20:39:16 EEST
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Product Code	Description Of Product
90110	POLYMED Abdominal Drainage Set 20FG
90111	POLYMED Abdominal Drainage Set 24FG
90112	POLYMED Abdominal Drainage Set 26FG
90113	POLYMED Abdominal Drainage Set 28FG
90114	POLYMED Abdominal Drainage Set 32FG
90115	POLYMED Abdominal Drainage Set 36FG
90116	POLYMED Abdominal Drainage Set 22FG
90117	POLYMED Abdominal Drainage Set 30FG
90118	POLYMED Abdominal Drainage Set 34FG

Product Image

General Information:

Intended Use

The product is used to drain out and collect fluid from a space of the body. A cut is made in the skin and the catheter is passed through into the space to allow the fluid to flow out into collection bag.

Legal Manufacturer-

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

Manufacturing Site-

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

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

Certification:

Certification	Notified Body
CE Certificate Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III **CE Certificate No.: G1 041938 0007 CL 041938 0010 Rev. 02**	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 Rev.03**	

Device Classification:

- As per the "Classification criteria" Annexure- IX of the Council Directive 93/42/EEC as amended by 2007/47/EC the Abdominal Drainage 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 1.1 of Annexure IX.
- This device penetrates inside the body through the surface of body with the aid or in the context of a surgical operation hence it is "Surgically Invasive Device" as per 1.2 of Annexure- IX.
- As per Rule- 7 of Annexure- IX of Council Directive 93/42/EEC as amended by 2007/47/EC all surgically invasive devices intended for short-term use are in Class IIa. Hence Abdominal Drainage Set is classified as Class IIa Medical Device.

Device Description:

- Soft abdominal drainage catheter approx. 100cm with graduated collection bag of 2000 ml capacity, drainage valve.
- Approx. 50cm soft & smooth PVC catheter with atraumatic & rounded open distal end & smooth eyes with markings at 2cm interval from the last eye.
- Various sizes in Abdominal Drainage Set are available. Available sizes are: 20FG, 22FG, 24FG, 26FG, 28FG, 30FG, 32FG, 34FG & 36FG.
- Radio opaque line on the catheter to facilitate easy location of tube.
- Specially designed handle to hold the collection bags.

Approved Materials of Constructions:

S. No.	Parts Where Material is used	Base Material
1	Collection Bag	PVC sheet
2	Catheter	PVC granules
3	Outlet Connector	PVC granules
4	Outlet (Sky Blue)	PVC granules
5	Hard Connector	Acrylonitrile Butadiene Styrene
6	Hanger	HDPE
7	Hanger Dori	Nylon
8	Hook	Acrylonitrile Butadiene Styrene

Sterilization Method:

Sterilized using Ethylene Oxide

Shelf Life:

Five years from the date of manufacturing

Standards Compliance:

Document Code	Document Description
EN ISO 13485:2016+ A11:2021	Quality system - Medical Devices - Requirements for the Regulatory Purposes
EN ISO 14971:2019/ A11:2021	Application of risk management to medical devices
IEC 62366-1:2015 / Amd 1:2020	Medical Devices – Application of usability engineering to medical devices
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
EN ISO 11737-1:2018/A1:2021	Sterilization of health care products -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products.
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.
EN ISO 11607-1:2020/ A1:2023	Packaging for terminally sterilized medical devices – requirements for materials, sterile barrier & packaging systems.
EN ISO 11607-2:2020/ A1:2023	Packaging for terminally sterilized medical devices – Validation requirements for forming, sealing and assembly process.
EN ISO 15223-1:2021	Symbols to be used with medical devices labels, labeling and information to be supplies
ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
EN ISO 10993-1:2020	Biological evaluation of medical devices – Evaluation and testing within a risk management process.

Reference to QMDS Documents:

Document Title	Polymed Internal Document Reference
Technical File	PML/MD/TF/27
Risk Management	PML/MD/RA/27
Clinical Evaluation	PML/MD/CER/27
DOC	F/QA/176

Packaging Characteristics:

The product is packed in unit pouch (Soft blister), which is made of polypropylene & polyethylene film and medical grade paper. The medical grade paper is designed to allow maximum exchange of ethylene oxide, air and moisture.

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 natural rubber latex or DEHP plasticizer.
- Any substances of animal origin e.g., BSE/TSE are not used during manufacturing.