

SRN: IT-MF-000025691

TECHNICAL DATASHEET**CODE: M90126****A/V universal blood line****CLASSIFICATION**

TECHNICAL FILE	BLD - SETS AND ACCESSORIES FOR EXTRACORPOREAL BLOOD MANAGEMENT
DECLARATION OF CONFORMITY	EU-DoC-BLD
CLASS RISK	Ila - Rule 2
EMDN CLASSIFICATION	F020199
GMDN CLASSIFICATION	34999
BASIC UDI-DI (MDR - Annex VI, Part C)	803377232BLD-HML8E
UDI-DI	8056992330832

TECHNICAL CHARACTERISTICS**Arterial line**

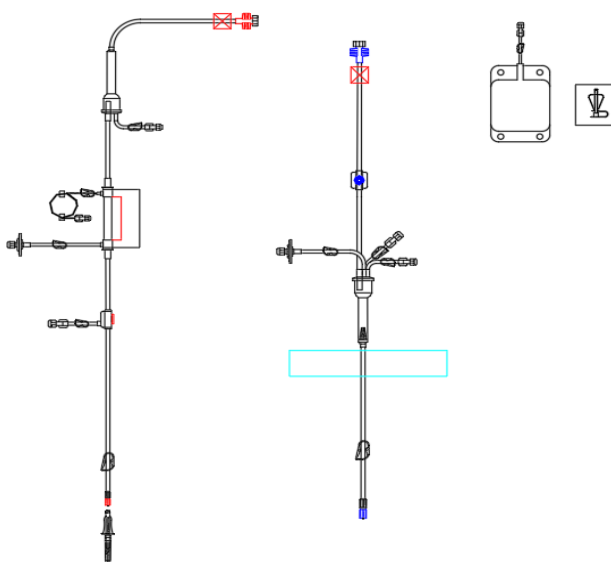
Filter connection via Female Twist-Lock connector
 Connection to vascular access via
 Pump segment [mm] 8x12
 Arterial drip chamber (pre-filter)
 Sampling port
 Heparin line
 Arterial trasducer protector
 Arterial spike

Venous line

Filter connection via Female Twist-Lock connector
 Drip chamber with particle filter
 Connection line for drug administration
 Venous trasducer protector
 Sampling port

Optional accessories

Drain bag 2 liters
 Waste hook

CONFIGURATION**Materials:** PVC, PP, PE, ABS, SILICONE, PTFE, PC, PES**PACKAGING TECHNICAL CHARACTERISTICS**

Pouch material	Shipping box material	Box pieces	Sterilization Method	Validity
Medical paper/Film	CARDBOARD	24	Ethylene oxide	THREE years

INTENDED USE

HEMODIALYSIS LINE: lines used in hemodialysis treatment.

PRINCIPLES OF OPERATION

The blood is extracted from an artery of the patient by needles, cannulas or catheters, and conveyed into the arterial line. The BLD devices are equipped with a pump section, which is inserted in a special seat of the peristaltic pump of the active medical device that manages the treatment, whose rotation cyclically occludes the tube lumen ensuring the necessary flow to the blood to be able to carry out the treatments required. The arterial line is normally connected to a filter (hemodialyser, plasma filter, hemoconcentrator, heat exchanger, oxygenator or other similar devices), which allows the desired blood treatment to be carried out. The venous line is connected to the outlet of the filter, which conveys the blood thus treated to another vascular access of the patient (needles, cannulas or catheters), causing it to be returned to the bloodstream.

INSPECTIONS

The production of SETS AND ACCESSORIES FOR EXTRACORPOREAL BLOOD MANAGEMENT is managed under the Medica Group Quality System certificate UNI EN ISO 9001:2015 ed UNI CEI EN ISO 13485:2021, according to the applicable SOPs (PG, Procedure Gestionali). All the devices undergo leakage tests.

PRODUCTION ENVIRONMENT

All manufacturing activities carried out for BLD devices, including:

- Plastic tubing extrusion and plastic parts moulding;
- Tubing sets assembling and inspection;
- BLD devices final assembling, inspection and single packaging are carried out in controlled contamination areas (clean room) ISO 8 classified, according to ISO 14644, managed in compliance with PG6401 (Management of work environment).

LABELING

Each package and every single shipping box is provided with a label, including data for the identification of the device (code, batch number, manufacturing date, expiry date, number of items and dimensions) and symbols complying with ISO 15223-1 standard.

Each multiple package is provided with a IFU (Instructions for Use) sheet with symbols complying with ISO 15223-1 standard.

PACKAGING

The packaging is compliant with Standard ISO 11607-1, ISO 11607-2 and ISTA 2A.

BIOCOMPATIBILITY

SETS AND ACCESSORIES FOR EXTRACORPOREAL BLOOD MANAGEMENT underwent biocompatibility tests according to their intended are complaint to UNI EN ISO 10993.

STORAGE AND HANDLING

The device must be kept away from heating sources, light and humidity. Handle with care, avoid shocks and falls.

DISPOSAL CONDITIONS

Disposal must take place in accordance with Italian Presidential Decree 254/2003 (implementation of Art. 24 L 179/2002) or according to the legislation in force in the country of use. The used devices must however be considered as hospital waste containing potentially infectious material.