

1. PRODUCT DESCRIPTION

Measured Volume Set consists of a graduated cylindrical burette to be filled with a specific volume. Measured Volume Sets consist of a floating auto shut- off valve that acts as floating indicator and automatically shuts- off the drain path, when the chamber gets empty to prevent trapping of air in the fluid line, it has soft and kink Resistant tube. The Major components are Graduated cylinder, PVC tube, hanger, spike, tube clamp, Roller clamp, Drip chamber, floater, Injection Site. It is a single use device. Duration of Use: Short term. Material of Composition: PVC, ABS, SS, Isoprene, PVDF material.

2. DEVICE CLASSIFICATION AND RULE

Measured Volume Set (w/o Needle) falls under Class-IIa (Rule 2) device as per EU MDR 2017/745 Annexure: VIII.
Rule 2 - Channeling or storing for eventual administration

Measured Volume Set (with Needle) falls under Class-IIa (Rule 7) device as per EU MDR 2017/745 Annexure: VIII.
Rule 7 - Surgically invasive devices intended for short-term use (> 60 min <30 days)

3. PRODUCT CHARACTERISTICS

Measured Volume Administration Set is used for the infusion of I.V. fluids and fluid-derivatives. It is made of calibrated measured volume chamber to administer measured quantity of fluids. It is Incorporated with a floating auto shut off valve for automatically shutting of the drain path when Chamber is empty. It also acts floating indicator.

It is having extra strong spike and bacteria barrier at air inlet on measuring cylinder. It is kinking Resistant tubing, strong roller clamp with provision to hold the tube for changing the fluid Container without disturbing the flow rate. E.T.O sterilized and Pyrogen free

- Micro drip with drop size of 60 drops per ml.
- Burette chamber is made of bio-compatible medical grade transparent polymer, suitable for infusion of all types of fluids.
- Design hanger facilitates the hanging of complete device on the I.V. stand.

- Floating auto shut off valve acts as floating indicator and automatically shut off the drain path to prevent air in line
- Roller controller provides accurate flow control.
- No-kink device prevents the kinking of tube during transportation.
- Separate plugs for extra medication and continuous change over.
- Sterile, individually packed.

4. INTENDED USE

Measured Volume Infusion Set intended for intravenous infusion of I.V. Fluids and parenteral drugs. It is used to deliver a fixed volume of IV fluid at a fixed rate.

5. PRODUCT VARIANTS

Following variants are available for the products

S.No.	Product	Gauge/Size	GMDN Code	Classification
1.	Measured Volume set	100ml, 110ml &150ml	12159	IIa

6. PRODUCT SPECIFICATION

Type	Capacity	Packing Inner/ Outer Unit
Vented	60 drops/ml	25/200
Non-Vented	60 drops/ml	25/200

7. PACKAGING DETAILS AND SPECIFICATIONS

ITEM	MATERIAL
Primary Packing	Pouch Packaging
Inner Carton	Kraft Pulp Paper
Master Carton	Kraft Pulp Paper

8. COMPLIANCE INFORMATION

Manufacturing Site Information:

Disposafe Health and Life Care Ltd., Plot No. 1 & 2,Phase-II Sec-59, Ballabhgarh, Faridabad-121004, Haryana (INDIA)

Drug Manufacturing License No.: MFG/MD/2019/000106

QMS Certification: EN ISO 13485:2016

CE Marking: TUV-SUD Product Services GmbH