

OUR PRIORITY  
IS  
PATIENT & CLINICIAN  
**SAFETY**



*Adding Value to Human Lives....*



Europe



**ANVISA**  
Agência Nacional de Vigilância Sanitária

Brazil



India

# Certificates

## CE Mark (EU-MDR)

## ISO 13485 : 2016

ZERTIFIKAT ◆ CERTIFICATE ◆ CERTIFICADO ◆ СЕРТИФИКАТ ◆ 認證證書



Product Service



**EU Quality Assurance Certificate (MDR)**  
Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A (Class IIa Devices)  
**No. G20 118060 0002 Rev. 01**

**Manufacturer:** **Trident Mediquip Limited**  
Plot No. C-13/13, Road No. 12A  
Near Shukla dairy  
Hojiwala Industrial Estate  
Sachin-Palsana Highway  
Surat, Gujarat 394230  
INDIA

SRN Manufacturer - IN-MF-000027535

**Authorized Representative:** mdi Europa GmbH  
Langenhagener Str. 71, 30855 Langenhagen, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. The Notified Body confirms that the class IIa devices in question conform to the technical documentation and meet the requirements of this Regulation which apply to them. Details on device categories covered by the quality management system are described on the following page(s).  
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex XI Part A of this regulation with a positive result.  
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.  
The certified quality assurance system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.  
For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G20\\_118060\\_0002\\_Rev\\_01](http://www.tuvsud.com/ps-cert?q=cert:G20_118060_0002_Rev_01)

<b>Report No.:</b>	TPS3317_CN
<b>Preceding Certificate No.:</b>	G20 118060 0002 Rev. 00
<b>Valid from:</b>	2024-07-02
<b>Valid until:</b>	2029-02-12
<b>Date of Initial Issuance:</b>	2024-02-13

**Issue date:** 2024-07-02

  
 Christoph Dicks  
 Head of Certification/Notified Body

Page 1 of 2  
TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123  
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ CERTIFICADO ◆ СЕРТИФИКАТ ◆ 認證證書



Product Service



**Certificate**  
**No. Q6 118060 0001 Rev. 01**

**Holder of Certificate:** **Trident Mediquip Limited**  
Plot No. C-13/13, Road No. 12A  
Near Shukla dairy  
Hojiwala Industrial Estate  
Sachin-Palsana Highway  
Surat, Gujarat 394230  
INDIA

**Facility(ies):** **Trident Mediquip Limited**  
Plot No. C-13/13, Road No. 12A, Near Shukla dairy, Hojiwala Industrial Estate, Sachin-Palsana Highway, Surat, Gujarat 394230, INDIA

See Scope of Certificate

**Certification Mark:**



**Scope of Certificate:** **Manufacturing, Distribution and Sales of Sterile Administration Kits, Peripheral IV Catheters and Cannulas.**  
**Applied Standard(s):** ISO 13485:2016  
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A1:2021)  
Medical devices - Quality management systems - Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q6\\_118060\\_0001\\_Rev\\_01](http://www.tuvsud.com/ps-cert?q=cert:Q6_118060_0001_Rev_01)

<b>Report No.:</b>	TPS3317_CN
<b>Valid from:</b>	2024-07-02
<b>Valid until:</b>	2027-02-12

**Date,** 2024-07-02

  
 Christoph Dicks  
 Head of Certification/Notified Body

Page 1 of 1  
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## Awarded by Government of India



सरपंच चयने

Government of India / भारत सरकार  
Ministry of Commerce and Industry / वाणिज्य और उद्योग मंत्रालय  
Department of Commerce / वाणिज्य विभाग  
Directorate General of Foreign Trade / विदेश व्यापार महानिदेशालय

मान्यता प्रमाणपत्र  
Certificate of Recognition

एक सितारा निर्यात हाउस  
One Star Export House



मेसर्स TRIDENT MEDIQUIP LIMITED  
(आई ई सी AAHCT5650R जिम्का आयकर पैन AAHCT5650R) को विदेश व्यापार नीति, 2023 के प्रावधानों के अनुसार एक सितारा निर्यात सदन का स्तर प्रदान किया जाता है। यह प्रमाण पत्र, प्रक्रिया पुस्तक(2023) में दी गयी शर्तों के निहित 5 वर्षों की अवधि के लिए दिनांक 01/10/2023 से 31/03/2028 तक वैध होगा।

M/s TRIDENT MEDIQUIP LIMITED  
(IEC AAHCT5650R having Income Tax PAN AAHCT5650R) are hereby accorded the status of One Star Export House in accordance with the provisions of the Foreign Trade Policy, 2023. This Certificate is valid for a period of 5 years effective from 01/10/2023 to 31/03/2028 subject to the conditions prescribed in Hand Book of Procedures (2023)

तारीख /Date: 11/10/2023  
स्थान /Place: GUJARAT  
(फाइल /File No.): SRTSTATAPPLY00000480AM24

Abhimanu Sharma  
Joint DGFT

This is a system generated digital certificate and it can be verified by scanning the QR Code or by UDIN on the DGFT Website (<https://www.dgft.gov.in>).

# About Us

**Trident Mediquip Limited (TML)** is a leading **Manufacturing Facility** of Safety IV. Catheter/Safety IV. Cannula, Safety Administration Set (with Air-Lock Mechanism) and other Delivery Access Devices. All of our Vascular Access devices are **CE mark (EU-MDR)**. Our Manufacturing Facility operations and activities are accredited with **ISO 13485:2016** Certification (by TUV SUD). All the manufacturing activities are carried out with strictly in compliance with EU-MDR/2017/745. TML is a manufacturing facility which adheres strictly to **SA8000** (Social Accountability 8000) compliances. Furthermore, TML is one of the leading manufacturing facilities from India, which has received the **Star Export House** Award issued by Government of India.

At  **TRIDENT™  
MEDIQUIP** We believe in



Compliance with high manufacturing standards



Fulfillment of commitment to our customers



Value addition to human lives via our premium quality products

EXPORTING TO  
**50+ COUNTRIES**  
WORLDWIDE



# Manufacturing Facility

Manufacturing Facility



Injection Moulding



AI-Powered Manufacturing



Class 10,000 Manufacturing



- **Class 10,000 Clean Room** Manufacturing
- **In-house Injection Moulding** of various medical disposables under controlled environment
- **In-house Quality Control Laboratory** Equipped with world class testing machineries
- **In-house Sterilization Facility**
- **In-house Product Development** and **Designing** Team
- **EU-MDR** Certified Manufacturing Facility



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## Safety IV Catheter / Administration Set

### Safety IV Catheter with Double Safety Mechanism

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### Safety Administration Set

Alphaset PRIME ----- Page No. 9

Alphaset ECO ----- Page No. 11



## Photosensitive / Lightproof Administration Set

Alphaset SENSO ----- Page No. 12

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## Standard Products

Standard Administration Set ----- Page No. 14

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Double Safety Mechanism



Snap-Fit Cap

## Safety IV Catheter / IV Cannula with

### DOUBLE SAFETY MECHANISM



#### DOUBLE PROTECTION

- Revolutionary Designed World's First Safety IV Catheter with DOUBLE PROTECTION.
- Provides Double Protection against Needle Stick Injuries and Inadvertent Deactivation.
- Conforms to the United States OSHA's Needle-Stick Safety and Prevention Act.
- Conforms to EC Directive 2010/23/EU for Prevention of Sharp Injuries.



#### PAINLESS INSERTION

- Ultra-Sharp Triple Facet Bevel for Smooth & Painless Venipuncture.
- Unique Engineering of Heel Distance between Catheter Tip and Needle's Bevel for Smoother Insertion.



#### DOUBLE FLASHBACK / NOTCH NEEDLE

- Notch in the Needle ensures First Stick Success with quick visualization of Blood inside the Catheter and the Flashback Chamber.



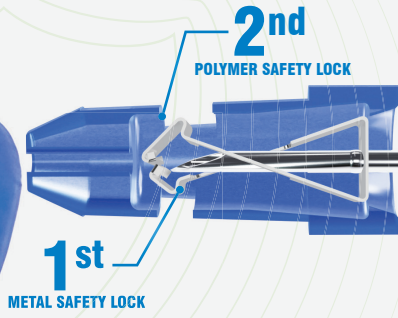
#### SNAP-FIT CAP

- Single Finger Operation.
- Ultra Flexible



#### FLASHBACK CHAMBER - TRANSPARENT

- Transparent Flashback Chamber for Immediate Confirmation of Venipuncture.



# CLINICIAN SAFETY

## IS OUR PRIORITY

Needle Sizes	Colour Code	Catheter Diameter (mm)	Catheter Length (mm)
14 G	ORANGE	2.10	45
16 G	GRAY	1.80	45
17 G	WHITE	1.50	45
18 G	GREEN	1.30	45
20 G	PINK	1.10	32
22 G	BLUE	0.90	25
24 G	YELLOW	0.70	19

**Catheter Material**  
TEFLON (FEP/PTFE) , PUR

SCAN FOR



DETAILED  
PRODUCT VIDEO

PACKING  
STYLE

1 Piece / Peel Open Blister Pack  
100 Packs / Mono Box  
10 Mono Box / Shipping Carton



# ALPHA<sup>+</sup>EN<sup>®</sup> SAFE

Without Wings and Without Injection Port



Double Safety Mechanism

FEATURES

## Safety IV Catheter / IV Cannula with

### DOUBLE SAFETY MECHANISM

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#### DOUBLE PROTECTION

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- Transparent Flashback Chamber for Immediate Confirmation of Venipuncture.



# Alphaset<sup>®</sup> PRIME



FEATURES



Air Lock Mechanism

## Safety Administration Set with

### AIR-LOCK MECHANISM

CE0123



- Alphaset<sup>®</sup> PRIME is **100% PVC Free**.
- Innovative **Air-Lock** mechanism, designed to only allow fluid to pass and prevents the line from running dry.
- According to a prominent Market Research, Administration Set with Air-Lock Mechanism provides **Peace of Mind to Clinicians** by relieving them from **Re-Priming**.<sup>(1)</sup>
- **Environment Friendly** - Alphaset<sup>®</sup> PRIME is 100% free from phthalates and PVC. Phthalates are among 20 Toxic Chemicals on the **EPA's** high priority chemical substance proposal.<sup>(2)</sup>

1. Key Group Consultative Market Research : New PVC/DEHP free IV Sets : New Product Concept & Conjoint Study. January 14 2021.
2. US Environmental Protection Agency : Phthalates Action Plan.



#### AIR-LOCK MECHANISM

- Designed to only allow fluid to pass and prevents the line from running dry.



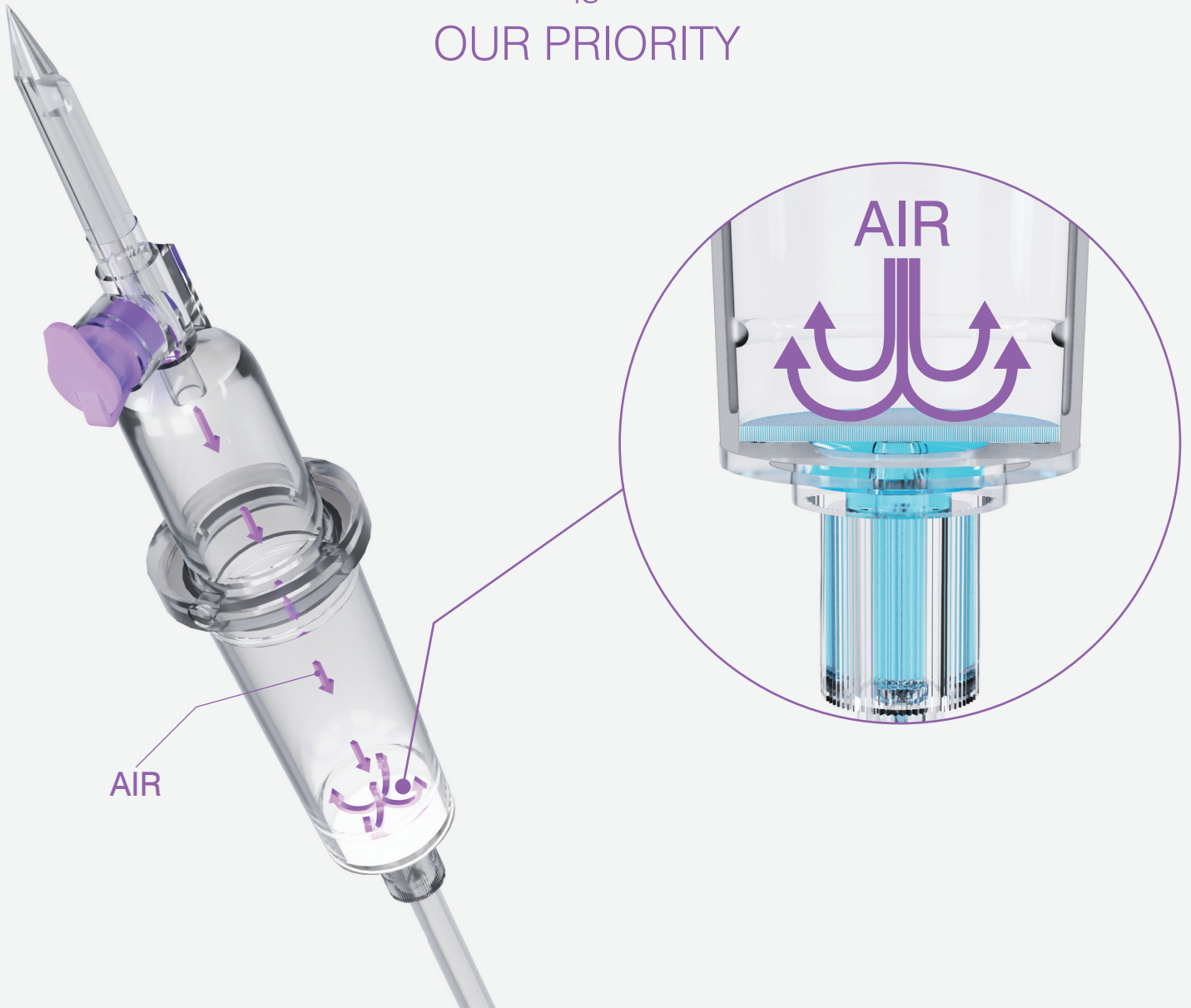
#### LUER LOCK - RE-PRIMING

- Hydrophobic Priming Filter Cap to Prevent Fluid Leakage.



# PATIENT SAFETY

IS  
OUR PRIORITY



SCAN FOR



DETAILED  
PRODUCT VIDEO

Parameters	Alphaset PRIME	Alphaset ECO
Air-Lock Mechanism	Available	Available
Chamber Design	Double Chamber	Single Chamber
Chamber Capacity	15ml	8ml
Roller Body	Spike Docking	Standard
Packaging Style	1 Pcs. / Pack 10 Packs / Polybag 10 Polybag / Shipper	1 Pcs. / Pack 25 Packs / Polybag 20 Polybag / Shipper





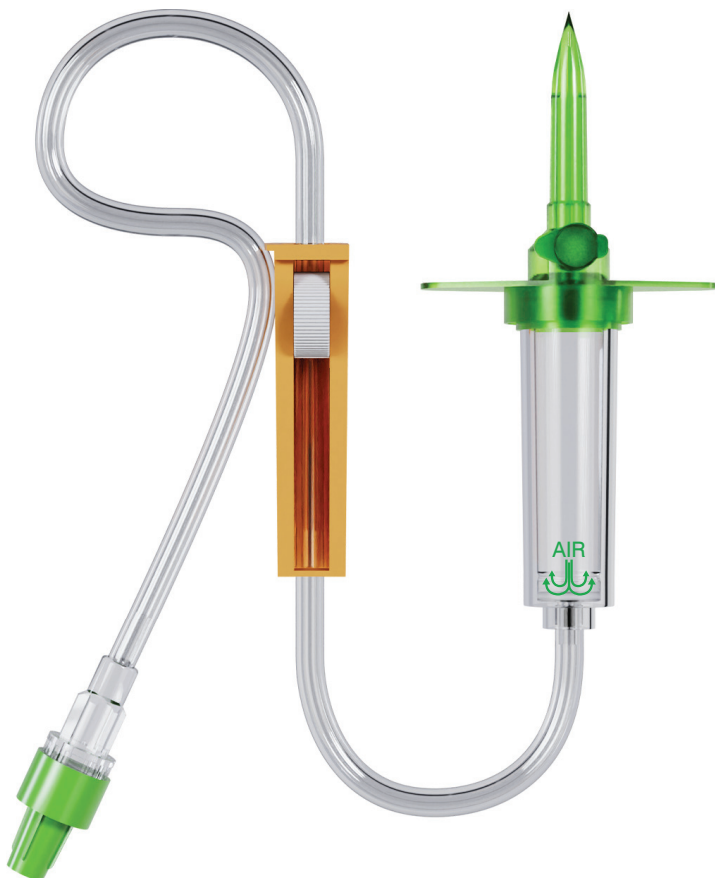
FEATURES



Air Lock Mechanism

# Safety Administration Set with

## AIR-LOCK MECHANISM



- Alphaset® ECO is **100% Phthalate Free**.
- Innovative **Air-Lock** mechanism, designed to only allow fluid to pass and prevents the line from running dry.
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### AIR-LOCK MECHANISM

- Designed to only allow fluid to pass and prevents the line from running dry.

## PATIENT SAFETY

IS OUR PRIORITY





# PHOTOSENSITIVE

Safety Administration Set  
with

**AIR-LOCK MECHANISM**

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EU-MDR



- Ultra Protective **Lightproof Photosensitive** Drip Chamber.
- Innovative **Air-Lock** mechanism, designed to only allow fluid to pass and prevents the line from running dry.
- According to a prominent Market Research, Administration Set with Air-Lock Mechanism provides **Peace of Mind to Clinicians** by relieving them from **Re-Priming**.<sup>(1)</sup>
- **High Volume** Capacity.
- **Protects** Drug Potency from UV Exposure.

1. Key Group Consultative Market Research : New PVC/DEHP free IV Sets : New Product Concept & Conjoint Study. January 14 2021.

## FEATURES



**Air Lock Mechanism**

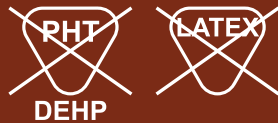
**PACKING STYLE**

**1 Pcs. / Pack**  
**10 Packs / Polybag**  
**10 Polybag / Shipper**

# STANDARD ADMINISTRATION SET

WITH  
IN-LINE FILTER

# PHOTOSENSITIVE



CE0123

EU-MDR



#### DRIP CHAMBER - WINGED SPIKE

- Ultra Protective Photosensitive Drip Chamber.
- Protects Drug Potency from UV Exposure.
- For Gravity Feed - 20 drop/ml



#### 0.2 Micron - IN-LINE FILTER

- Self Venting.
- Guaranteeing Superior Flow Rates.
- Fast Priming Performance.
- Better Mechanical Resistance with Pump Applications.
- 96hr Filtration.



#### LUER LOCK - RE-PRIMING

- UV Resistant Tubing Minimizes Decomposition of the Active Ingredients of Various Drug.
- Hydrophobic Priming Filter Cap to Prevent Fluid Leakage.

PACKING  
STYLE

1 Pcs. / Pack  
25 Packs / Polybag  
20 Polybag / Shipper



# STANDARD ADMINISTRATION SET

CE0123

EU-MDR



## FEATURES



Highly Accurate Flow Regulator



In-Line Filter

CE0123

EU-MDR



### DRIP CHAMBER - WINGED SPIKE

- Ultra Sharp Spike.
- Winged spike for better grip.
- For Gravity Feed - 20 drop/ml



### 0.2 Micron - IN-LINE FILTER

- Self Venting.
- Guaranteeing Superior Flow Rates.
- Fast Priming Performance.
- Better Mechanical Resistance with Pump Applications.
- 96hr Filtration.



### FLOW REGULATOR - HIGHLY ACCURATE

- Highly accurate control of Flow Rate.
- High Stability in Infusion Delivery.
- No Electrical Power is Required.
- Operating range from 20ml to 250ml/hr.

PACKING STYLE

1 Pcs. / Pack  
25 Packs / Polybag  
20 Polybag / Shipper

## INJECTION SITE



Injection Y-Site



Needle Free Y-Site

## LUER CONNECTION



Luer Slip Connector



Fixed Luer Lock Connector



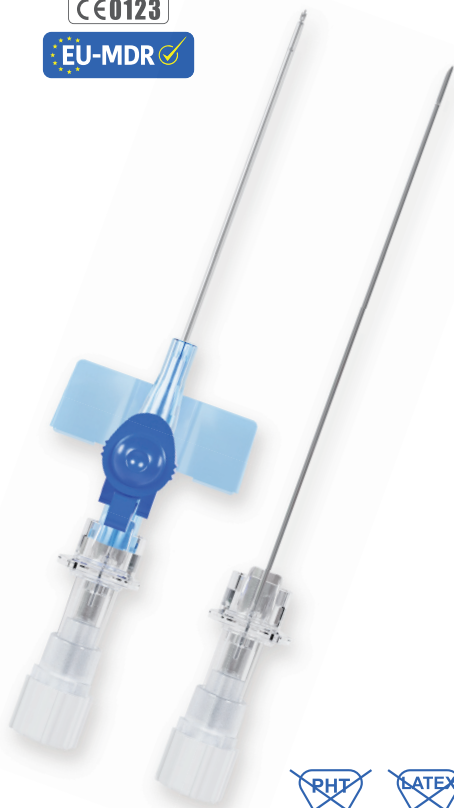
Rotating Luer Lock Connector



# IV CATHETER / IV CANNULA

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EU-MDR



**MEDITOR**<sup>®</sup>

With Wings and With Injection Port

## PAINLESS INSERTION

- Ultra-Sharp Triple Facet Bevel for Smooth & Painless Venipuncture.
- Unique Engineering of Heel Distance between Catheter Tip and Needle's Bevel for Smoother Insertion.



## SNAP-FIT CAP

- Single Finger Operation.
- Ultra Flexible



## FLASHBACK CHAMBER - TRANSPARENT

- Transparent Flashback Chamber for Immediate Confirmation of Venipuncture.

**ALPHA**<sup>®</sup>

Without Wings and Without Injection Port



## PAINLESS INSERTION

- Ultra-Sharp Triple Facet Bevel for Smooth & Painless Venipuncture.
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## FLASHBACK CHAMBER - TRANSPARENT

- Transparent Flashback Chamber for Immediate Confirmation of Venipuncture.

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**PACKING  
STYLE**

**1 Piece / Peel Open Blister Pack  
100 Packs / Mono Box  
10 Mono Box / Shipping Carton**



# BURETTE SET

## Burette Set - Measured Volume Set

CE0123



- Chamber Capacity of 110-150 ml.
- Medical Grade PVC Material.
- With or without Needle.
- With Floating Auto Shut Off Valve.
- Latex / Non Latex Option.
- Sterilized by ETO (Ethylene Oxide Gas).



Automatic Shut Off Floating Valve



Y Site



Smooth Flow Control

## Blood Administration Set

- Medical Grade PVC Soft Tubing.
- 200 Micron Filter.
- Disposable and Non-Toxic.
- Sterilized by ETO (Ethylene Oxide Gas).
- Efficient Roller Controller for Better Flow.
- With or Without Needle.

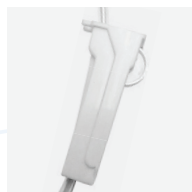
CE0123



Non Kinkable Chamber



Y Site



Smooth Flow Control



**PACKING  
STYLE**

**1 Pcs. / Pack  
10 Packs / Polybag  
10 Polybag / Shipper**

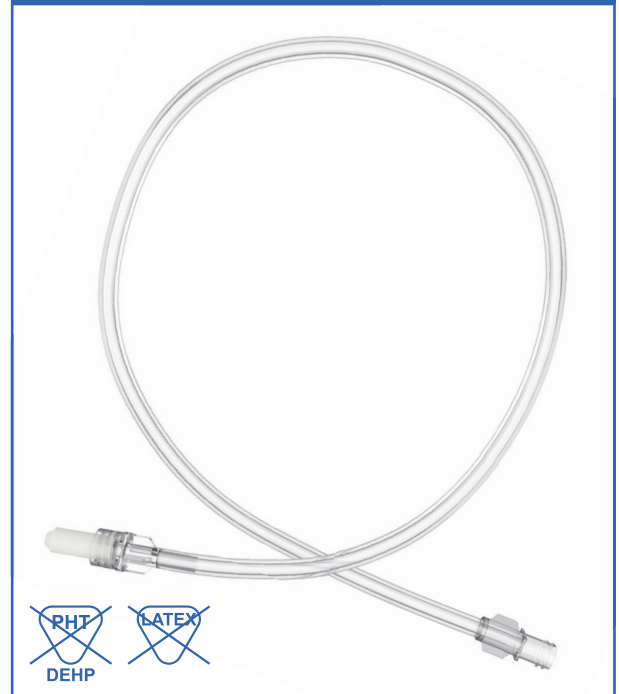


# EXTENSION LINES

## Extension Line with Flow Regulator



## Extension Line



## Extension Line with 3 Way Stopcock



NOW  
AVAILABLE

(20 cm, 50 cm, 100 cm,  
120 cm and 150 cm)

**PACKING  
STYLE**

**1 Pcs. / Pack  
25 Packs / Polybag  
8 Polybag / Shipper**

- Comes with an in-line flow regulator allowing precise adjustment of infusion rate (commonly 5–250 ml/hr), reducing the risk of under or over-infusion.
- Designed for consistent and controlled flow of IV fluids, making it ideal for long-term therapies and critical care.
- Universal luer lock and luer slip connectors for compatibility with most IV systems, syringes, and catheters.
- Engineered with medical-grade PVC and DEHP-free variants to maintain sterility and chemical resistance.





*Adding Value to Human Lives....*

Follow Us On



 **Corporate Office :**

2004, 2nd Floor, North Extension, Ring Road, Falsawadi, Surat - 395003, Gujarat, INDIA.

 **Manufacturing Facility (1)**

C-13/13, Hojiwala Industrial Estate,  
Sachin, Surat - 394230, Gujarat.

 **Manufacturing Facility (2)**

D-25/20, Hojiwala Industrial Estate,  
Sachin, Surat - 394230, Gujarat.



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