DECLARATION

We, **Global Medikit Limited**, hereby declare that our medical device:

Device Name: *Gloflon Safety – Safety I.V. Catheter with Injection Valve and with Wings*

Complies with the following specifications:

1. **Material**: Manufactured from **polyurethane (PUR)** with **3 contrast lines** for radiographic visibility.
2. **Flexible Wings**: Equipped with **flexible wings** that are **resistant to repeated bending maneuvers**, ensuring durability and ease of handling.
3. **Lumen**: Designed with a **lumen of minimal risk of obstruction**, which is **flexible** and **resistant to repeated bending maneuvers**, ensuring consistent and safe fluid flow.
4. **Thermoelastic Property**: The catheter is constructed with **thermoelastic characteristics,** enhancing **patient comfort** and ensuring **reliable** performance during clinical use.

For Global Medikit Limited

GLOBAL MEDIKIT LTD SELAQUI DEHRADUN

Digitally signed by Dolgopol Iulian
Date: 2025.12.18 09:12:34 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Name: SAMAR KESHARI JENA

Designation: Manager, Quality Assurance

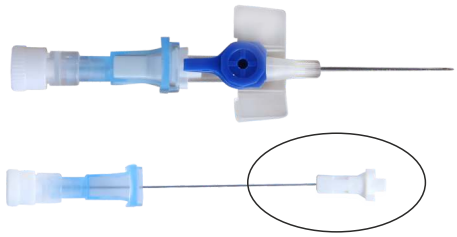
Date: 20.08.2025

Gloflon Safety®

Safety I. V. Catheter with Injection Valve and Wings

I.V. Catheter with injection valve and wings with added safety feature for prevention of needle stick injury.

- Safety feature for complete protection from needle stick injury.
- Passive, irreversible activation of safety mechanism.
- No change in insertion technique required.
- Stainless steel, silicone tipped needle for smooth penetration.
- Injection port with one way silicone injection valve.
- Specially designed protection cap with a recessed plug to cover the injection port and minimize contamination.
- Angled and grooved wings for secure fixation.
- Radio-opaque lines for accurate radiographic detection.
- Luer cap for blocking the catheter when not in use.
- 6% luer taper for compatibility with all standard devices.
- Disposable, sterile and non-pyrogenic.



Needle Safety Guard

Technical Specifications

Gauge	Colour Code	Catheter			Ref. No.	Qty. in carton
		Ext. Dia. (mm.)	Length (mm.)	Flow Rate (ml./min.)	Radiopaque	Inner/ Outer
14	Orange	2.1	45	300	4580142G	100/1000
16	Grey	1.8	45	200	4580162G	100/1000
17	White	1.5	45	140	4580172G	100/1000
18	Green	1.3	45	90	4580182G	100/1000
20	Pink	1.1	33	61	4580202G	100/1000
22	Blue	0.9	25	36	4580222G	100/1000
24	Yellow	0.7	19	15	4580242G	100/1000
26	Purple	0.6	19	13	4580262G	100/1000

Gloflon Pro Safety™

with Needle Safety Clip

Safety I. V. Catheter with Injection Valve and Wings

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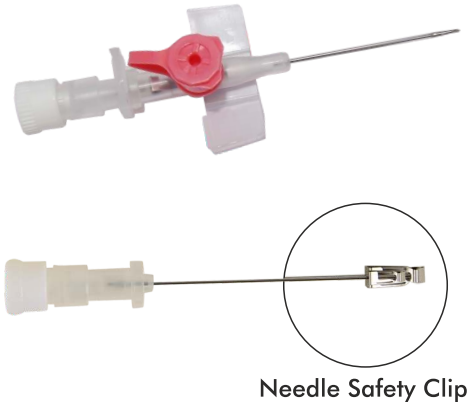
- Radio-opaque lines for accurate radiographic detection.
- Luer cap for blocking the catheter when not in use.
- 6% luer taper for compatibility with all standard devices.
- Disposable, sterile and non-pyrogenic.



Needle Safety Clip

Technical Specifications

Gauge	Colour Code	Catheter			Ref. No.	Qty. in carton
		Ext. Dia. (mm.)	Length (mm.)	Flow Rate (ml./min.)	Radiopaque	Inner/ Outer
14	Orange	2.1	45	300	4116142G	100/1000
16	Grey	1.8	45	200	4116162G	100/1000
17	White	1.5	45	140	4116172G	100/1000
18	Green	1.3	45	90	4116182G	100/1000
20	Pink	1.1	33	61	4116202G	100/1000
22	Blue	0.9	25	36	4116222G	100/1000
24	Yellow	0.7	19	15	4116242G	100/1000
26	Purple	0.6	19	13	4116262G	100/1000

Global Medikit Limited
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Ref. No: TDS – 01I, Revision No - 05

TECHNICAL DATA SHEET

Gloflon Safety®

(Safety I.V. Catheter with Injection Valve and with Wings)

Product Photograph

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GENERAL DESCRIPTION OF DEVICE

DEVICE BRAND NAME	**Gloflon Safety®**
DEVICE MODEL	Safety I.V. Catheter with Injection Valve and with Wings
DEVICE DESCRIPTION	Gloflon Safety® IV Catheters are over-the-needle, intravascular (IV) catheters. These devices include a radiopaque catheter, needle, needle hub, safety needle shield, and flash chamber with removable vent plug. The needle and catheter are protected by a needle cover. The flash back chamber provides confirmation that the device has entered the vessel. The needle tip is protected when the needle is removed, reducing the risk of accidental needlestick injury.
INTENDED USE	I.V. Catheter is a device for access to the human circulatory system for the introduction of fluids or medicament and / or withdrawal of blood samples.
CLASSIFICATION	Class IIa as per Rule 7of Annex VIII of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
SIZE AVAILABLE	14G,16G,17G,18G,20G,22G,24G,26G
PATIENT POPULATION	Child, Adult

Brand Name	Product name	Specifications	Variant/Size	Reference No. Radio-Opaque
Gloflon Safety	I.V. Catheter with Injection valve and wings	FEP catheter, 60 GSM paper, 100 GSM Paper, Tyvek paper	14G	4580142G
			16G	4580162G
			17G	4580172G
			18G	4580182G
			20G	4580202G
			22G	4580222G
			24G	4580242G
			26G	4580262G

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DEVICE SPECIFICATIONS

- **Technical Specifications**

PARAMETER	TOLERANCE	SPECIFIED VALUE							
GAUGE		**14G**	**16G**	**17G**	**18G**	**20G**	**22G**	**24G**	**26G**
Needle OD (in mm)	± 0.01	1.47	1.25	1.05	0.87	0.71	0.56	0.45	0.41
Needle Material	-	Stainless steel							
Needle Type	-	Back Cut							
Catheter OD (in mm)	+0.049, -0.05	2.1	1.8	1.5	1.3	1.1	0.9	0.7	0.6
Catheter Material	-	FEP (Radio opaque)							
Effective length (in mm)	±1 mm	45	45	45	45	33	25	19	19
Flow Rate ml/min	Not less than 80% for catheter OD≤1.0mm Not less than 90% for catheter OD≥1.0mm	300	200	140	90	61	36	15	13
Colour		Orange	Grey	White	Green	Pink	Blue	Yellow	Violet
Distance of Catheter Tip from Needle Bevel Heel	Mini. to Max.	0.1 to 1.0 mm							
Connecting Port	-	6% female Taper with luer lock facility.							

- **Features:**

- ❖ Radio-opaque catheter for easy insertion and X-ray detection.
- ❖ Needle safety guard automatically covers the bevel after withdrawal of needle from the hub, minimizing the risk of needle stick injuries.
- ❖ Easy identification of needle safety guard after covering needle tip due to color coding of needle hub.
- ❖ Stainless steel, siliconized needle for easy and smooth penetration.
- ❖ Robust, evenly, sharp, triple facetted beveled needle ensures least trauma and reliable insertion.
- ❖ Color coded injection port cap is provided for easy identification of gauge size.
- ❖ Injection port is provided with one way injection valve for extra medication by syringe without needle and to prevent back flow.
- ❖ Ergonomically designed luer lock facilitates instant secure closure immediately after penetration.
- ❖ Flexible angled wings allow easy fixation and prevent displacement of catheter over the patient's body.
- ❖ Transparent flashback chamber for easy visualization of blood.
- ❖ Sterile, non-pyrogenic, for single use.

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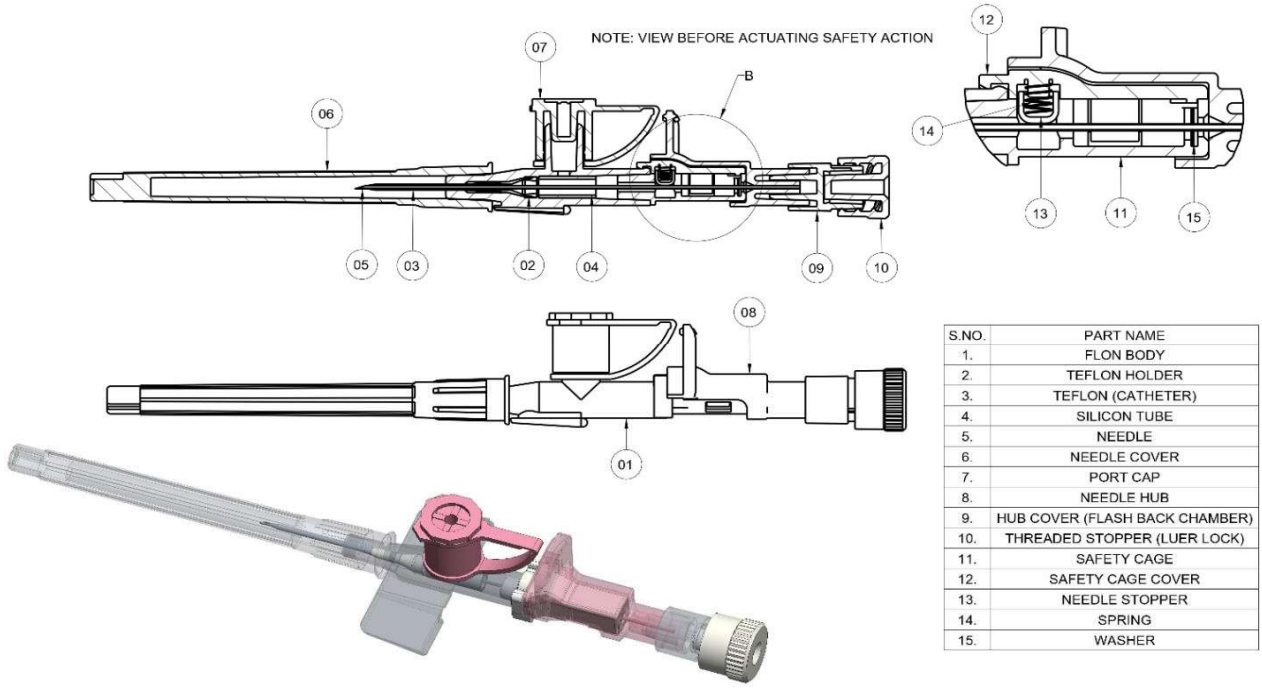
DEVICE DRAWING



S.NO.	PART NAME
1.	FLON BODY
2.	TEFLON HOLDER
3.	TEFLON (CATHETER)
4.	SILICON TUBE
5.	NEEDLE
6.	NEEDLE COVER
7.	PORT CAP
8.	NEEDLE HUB
9.	HUB COVER (FLASH BACK CHAMBER)
10.	THREADED STOPPER (LUER LOCK)
11.	SAFETY CAGE
12.	SAFETY CAGE COVER
13.	NEEDLE STOPPER
14.	SPRING
15.	WASHER

APPROVED MATERIAL OF CONSTRUCTION

S.no	Part name	Material used
1	Body (Wing Housing)	Polypropylene (PP)
2	Catheter Holder	Polyacetal (POM)
3	Catheter	Fluorinated ethylene propylene with 2RO Lines (FEP)/Polyurethane (PU) with 3RO Lines
4	Silicon Tube	Silicon Rubber
5	Needle	Stainless Steel (AISI 304)
6	Needle Cover	Polypropylene (PP)
7	Port cap	Linear Low-Density Polyethylene (LLDPE)
8	Needle Hub	Polypropylene (PP)
9	Hub Cover (Flash Back Chamber)	Polypropylene (PP)
10	Threaded Stopper	High Density Polyethylene (HDPE)
11	Safety Cage	Polyacetal (POM)
12	Safety Cage Cover	Polyacetal (POM)
13	Needle Stopper	Polypropylene (PP)
14	Spring	Stainless Steel (AISI 304)
15	Washer	Stainless Steel (AISI 304)

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PACKING SPECIFICATIONS

The Device is individually packed in PVC blister pack sealed with Medical Kraft paper, such 100 PCs. Are packed in inner carton Duplex board & such 10 inner cartons are packed in master carton i.e. Kraft pulp Paper.

Packing Details

Individually packed size	147 x 27.5 mm
Inner carton size	168 x 150 x 150 mm
No. of packed pieces in inner carton	100 pcs
Master carton size	765 x 320 x 178 mm
No. of inner carton in master carton	10 nos
No. of individually packed pieces in master carton	1000 pcs

STERILIZATION

The device is sterilized by Ethylene Oxide (EtO), A Concentration of 20:80 (ETO: CO2).

STORAGE CONDITION

Stored in at 5°C to 25°C temperature, keep away from moisture, direct light and heat sources.

SHELF LIFE

Shelf life of the finished product 5 years from the date of sterilization.

STANDARDS COMPLIANCE

ISO 13485:2016	Medical devices – quality management systems – requirements for regulatory purposes
ISO 14971:2019	Medical devices – application of risk management to medical devices
ISO 15223-1:2021	Medical devices – symbols to be used with medical device labels, labelling and information to be supplied – part 1: general requirements
ISO 20417:2021	Information supplied by the manufacturer of medical devices
ISO 10555-1:2013	Intravenous catheters – sterile and single- use catheters –Part 1: General requirements
ISO 10555-5:2013	Sterile, single-use intravascular catheters – Part: Over- needle peripheral catheters.
ISO 80369-7: 2016	Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications

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IEC 62366-1:2015	Medical devices - application of usability engineering to medical devices
ISO 11607-1:2019	Packaging for terminally sterilized medical devices – part 1: requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2019	Packaging for terminally sterilized medical devices – part 2: validation requirements for forming, sealing and assembly processes
ISO 10993-1:2018	Biological evaluation of medical devices – part 1: evaluation and testing within a risk management process
ISO 10993-7:2008	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
ISO 11135:2014	Sterilization of health care products – ethylene oxide – part 1: requirements for development, validation and routine control of a sterilization process for medical devices
ISO 14644-1:2015	Cleanrooms and associated controlled environments – part 1: classification of air cleanliness by particle concentration
ISO 14644-2:2015	Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
MEDDEV 2.7.1., Rev 4	Clinical evaluation: a guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC
ISO 11737-1:2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
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
MDCG 2020-6	Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC

Date: 06 August 2024

Samar Keshari Jena
Regulatory Affairs Manager
Global Medikit Limited

INSTRUCTIONS FOR USE LEAFLET

INSTRUCTIONS FOR USE

I.V. Catheter with Injection Valve and Wings

MEDIFLON/ANINA/KETHIN/MEDION/MEDIFLON PLUS/MEDIFLON PRO/ABOVAL/ GLOFLON/GLOTHIN/GLOFLON PLUS/GLODION/GLOVAL

DEVICE DESCRIPTION:

I.V. Catheters is over-the-needle, intravascular catheters which is a small, flexible tube designed to deliver I.V. medications and fluids to the patient or to withdraw blood samples. These devices include a radiopaque catheter, needle, wing housing, needle hub and flash chamber with removable vent plug. The needle and catheter are protected by a needle cover. These devices have flash chamber which provides confirmation that the device has entered the vessel. The devices are single use, sterile intravascular catheters designed to be inserted into a patient's vascular system to sample blood, monitor blood pressure, or administer fluids intravenously

MATERIAL:

Poly Propylene (PP), Fluorinated ethylene propylene (FEP), Poly-oxy methylene (POM),Stainless steel (SS),High density polyethylene (HDPE), silicon rubber, Linear Low Density polyethylene (LLDPE)

INTENDED PURPOSE:

I.V. Catheter is a device for access to the human circulatory system for introduction of fluids or medicament and / or withdrawal of blood samples.

INTENDED USER: Use is restricted to qualified doctor or a paramedic.

INTENDED PATIENT POPULATION: All patient population irrespective of age and gender.

INDICATIONS:

- Infusion of I.V. solutions.
- Intermittent intravenous Drug Administration.
- To maintain hydration and /or correct dehydration if patient is unable to take sufficient volume of oral fluids.

CONTRAINDICATIONS:

- Use in patients allergic/hypersensitive to any of the materials used in device.
- Administration of high viscous fluids.
- Large Blood transfusion.

INSTRUCTIONS FOR USE:

- Check the integrity of sterile barrier packaging and open the pack from area of peel.
- Remove the device, remove the needle cover and loosen the needle from the catheter.
- Insert the needle with the bevel facing up and angle between 10° to 30°.
- Observe the flash back of blood into needle hub and confirm the puncture of the vein.
- Lower the level of the catheter and advance a few millimeters further into the vein.
- Withdraw needle approximately 5mm.
- Advance the catheter further into the vein observing for continued flashback of blood along the catheter and the needle hub.
- Slightly withdraw the needle, apply pressure at the tip of the catheter to prevent any additional backflow of blood.
- Withdraw the needle completely and dispose directly into the sharps container to avoid unwanted injury due to needle.
- Secure the I.V. catheter with the help of a skin tape. Use the wings for better securement of device.
- Attach the threaded stopper at the end of I.V. catheter, when not in use. For infusion, connect the female luer port to the male luer of the infusion system.
- For extra medication fill the syringe with the required drug administration. Open the port cap and connect the injection port to the male luer of the syringe and push the plunger of syringe to give medication. Close the injection port with the help of the port cap.
- For withdrawal of blood, connect male luer of the syringe to the female luer port of the I.V catheter and pull the plunger slowly in outside direction.
- Discard the device as per the instruction provided in this IFU.

PRECAUTIONS:

- Open the sterile barrier pack only under aseptic conditions.
- NEVER TRY TO REINSERT THE PARTIALLY OR COMPLETELY WITHDRAWN NEEDLE.
- Close the port cap and stoppers when the device is not in use.
- Never rotate the needle or catheter while insertion
- The use of this product is restricted to a qualified doctor or a paramedic.
- Do not use if the sterile pack is opened or damaged.
- Dispose after single use.
- This product is for single use only; re-use could cause infection or cross-contamination.
- Store in a cool and dry place. Keep away from sunlight and rain.
- Exposure to elevated temperature and ultraviolet light to be avoided

WARNINGS:

- Read instructions before use.

GLOBAL MEDIKIT will not be responsible for any structural and functional damage to the device or packing cause due to improper transportation and material handling.

- The Product should not be reprocessed.
- The product is guaranteed, Sterile till the package has not been opened or damaged within the expiry date.
- Do not clean or re-sterilise.

ADVERSE EFFECTS:

Pain, discomfort, hives, bleeding, blanching, bruising, burning, allergic reaction from hypersensitivity to materials used in the device, local insertion site infection etc.

HAZARDS OF RE-USE:

Transmission of infection from one patient to another.

PACKAGING:

The device is packed in Blister film sealed with Tyvek paper/medical grade paper, inner carton i.e. duplex board& master carton i.e. craft pulp paper.

STERILIZATION:

Device is EO sterilized and sterilization is done by Global Medikit Limited.

STORAGE CONDITION:

Temperature Limit: 5°C to 25°C

DISPOSAL:

After use, this product may be a potential biohazard. Handle and dispose off in accordance with accepted medical practice and applicable local, state, and federal law and regulation.

REPORTING OF ADVERSE EVENTS:

In case of any serious adverse event please report the same to info@globalmedikit.in or regulatory@obelis.net

Note: For product used in EU also report to the competent authority of the Member State in which the user and/or patient is established.

Revision : 8 Date : 02/11/2022

MEDIKIT
The better life

	Manufacturer
EC REP	Authorised representative in the European Community
	Date of manufacture
	Use by / Expiry Date
LOT	Batch code
REF	Catalogue number
STERILE EO	Sterilized using ethylene oxide
	Do not resterilize
	Temperature limit
	Do not reuse
	Consult instructions for use
	Do not use if package is damaged and consult instructions for use
	Caution
MD	Medical Device
CE 0123	CE marking
UDI	Unique Device Identifier
SBS	Single sterile barrier system
	Non-Pyrogenic
	Keep Dry
	Keep Away from Sunlight

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Boulevard Général Wahis 53, 1030 Brussels, BELGIUM
Tel: +32 (2) 73 25 954 | Fax: +32 (2) 73 26 003
E-mail: regulatory@obelis.net

IFU
Device Name : I V CATHETER WITH INJECTION VALVE & WINGS
Brand Name : MEDIFLON/ ANINA/ KETHIN/ MEDION/ MEDIFLON PLUS/MEDIFLON PRO/ ABOVAL/ GLOFLON/ GLOTHIN/ GLOFLON PLUS/ GLODION/ GLOVAL
Dimension : Length 203 x width 140mm
Colour : BLACK
Material : Chromo art paper 70gsm

Artwork No.: GML/IFU/001/001, Rev-08, Date: 02/11/2022