

Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat al dispozitivelor medicale

nr. 62 din 16.09.2023

Solicitantul **FPC "SOGNO" S.R.L.**, cu sediul MD-2028, mun.Chișinău, str.Academiei, 2, tel.:(022) 72-75-25/
069501992, fax:(022) 73-83-42, e-mail: sognomd@gmail.com,
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive
medicale pentru introducerea și punerea la dispoziție pe piață a:

Conform Anexei nr.3 "Lista dispozitivelor medicale Poly Medicure Limited (Clasa Ila)"

Se anexează următoarele acte:

1. Certificat CE.
2. Declarație de Conformitate.
3. Scrisoarea autorizată a producătorului.
4. Declarație pe propria răspundere.
5. Lista dispozitivelor medicale.

Data: 16.09.2023

Semnătura



Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: **FPC "SOGNO" SRL**, cu sediul m. Chișinău, str. Academiei nr.2, Republica Moldova,
declar pe proprie răspundere, cunoscând prevederile art. 352¹, Codul Penal al Republicii Moldova cu privire la
falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivelor medicale:

Conform Anexei nr.3 "Lista dispozitivelor medicale Poly Medicure Limited (Clasa Ila)"

Sunt autentice și corespund realității.

Iarovoi Petru, Director



Semnătura

Data 16.09.2023

Lista dispozitivelor medicale Poly Medicure Limited (Clasa Ila)

Numarul de catalog	Denumire	Denumirea comerciala	Modelul	Tip dispozitiv	Cod GMDN
13261	LINIE DE EXTENSIE PENTRU PREPARATE FOTOSENSIBILE	—	150cm (OD-3.0mm x ID-1.0mm)	Dispozitiv terapeutic activ	12170
14106	SET PENTRU INFUZIE	—	150cm, cu reglator flux 0-250 ml/min	Dispozitiv invaziv	12170

Iarovoi Petru, Director

Semnătura



Poly Medicure Limited

Regd. Office : 232-B, 3rd Floor, Okhla Industrial Estate,
Phase-III, New Delhi - 110020 (INDIA)
T: +91-11-33550700, 47317000, F: +91-11-26321894, 26321839
E: info@polymedicure.com W: polymedicure.com
CIN: L 40300DL1995PLC066923



LETTER OF AUTHORIZATION

Ref.No. : PML/AL/22-23/6
Date: 20.01.2023

TO WHOM SO IT MAY CONCERN

We, **POLY MEDICURE LIMITED** having its principle office at Plot no. 104 -105 & 115-116, Sector-59, HSIIDC Industrial Area, Ballabgarh-121004 Faridabad (Haryana), INDIA is an established and reputable manufacturer and exporter of medical devices.

With this letter, we hereby authorize the below company to register, promote, distribute our product and to present quotations for tenders on its own behalf, provide sales, and to quote, sign and receive contracts in its own name for tender opportunities in the territory of Republic of Moldova.

FPC "SOGNO" SRL

Address: No 2 Academiei str., Chisinau, Republic of Moldova

We authorize the above-mentioned distributor to sell our products under the "**POLYMED**" brand name in the said territory for the following products

- a) IV Infusion Set
- b) High Pressure Extension Line

We further notify that this Letter of Authorization does not grant rights to **FPC "SOGNO" SRL** other than as described & declared here in above in this letter. *

If any act or omission is done by **FPC "SOGNO" SRL** beyond the powers conferred by this Letter of Authorization, no liability shall be attributable to Poly Medicure Limited and **FPC "SOGNO" SRL** will be fully responsible.

This authorization letter is valid for 5 years from the Date of issue.

This authorization is subjected to renewal on the basis of mutual consent and can be terminated by either party by giving 60 Days prior notice in writing.

Best Regards,


Sujit Kumar Gupta

(Associate Vice President-
International Sales & Marketing)

Poly Medicure Limited

Works : Plot No.104-105 & 115-116, Sector-59, HSIIDC Industrial Area, Ballabgarh, Faridabad - 121004, Haryana (INDIA)
T: +91-129-3355070, 4287000, F: +91-129-2307007, 2309102



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in Class IIa, IIb or III)

No. G1 041938 0007 Rev. 00

Manufacturer:

POLY MEDICURE LIMITED

Plot No. 104-105, Sector-59
HSIIDC Industrial Area, Ballabhgarh
Faridabad, Haryana 121004
INDIA

Product Category(ies):

IV Cannula/ Catheter with / without Safety Features, Infusion Sets, Burette Infusion Sets, Flow Regulators, Extension Lines, Luer Caps, Stylet (Obturator), CVP Manometers, Stop cock with/without extension line, Needle free connectors with/without extension line, Scalp vein (Winged Infusion) Set (with / without safety features), Insulin Syringe, Huber Infusion set with / without safety features, Over the Needle (OTN) Catheter, Arterial Cannula with/without Safety Features, Manifolds with/without Extension line, Mini-midline Catheter (Peripheral catheter), Transfusion Pump Set, Luer Adaptors, Blood Bags, Blood Collection Set with / without Safety Features, Blood Collection Needle & Holder, Transfusion Sets (BT Sets), Closed Wound Suction Unit, Yankaur Suction Set (Suction tube and/or Handle), Thoracic Drainage Catheter (with/without Trocar), Redon Drainage Tube, Abdominal Drainage Set, Under Water Seal Drainage System, Female catheter, Nelaton catheter, Foley Balloon Catheter, Irrigation Set, Levins tube, Infant Feeding Tube, Ryle's Tube, Stomach Tube, Umbilical Catheter, Feeding Bag, Mucus Extractor with/without Bacterial Filter, Suction Catheter, Nasal Oxygen Catheter/ Cannula, Oxygen Catheter, Guedel Airways, Endotracheal Tubes (Plain, Cuffed, Reinforced), Catheter Mount, Oxygen Mask, Nebulizer Mask, Venturi Mask, Blood Line Set, Fistula Needle with / without Safety features, Peritoneal Dialysis Transfusion Set, Peritoneal Dialysis Catheter Kit, High Pressure Vacuum Drainage Bottle.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: IND2019081_CN

Valid from: 2020-06-17

Valid until: 2024-05-26

Date, 2020-06-17

Christoph Dicks
Head of Certification/Notified Body

19 August 2023

EC DECLARATION OF CONFORMITY

We Poly Medicure Limited, Plot No. 104-105, Sector-59, HSIIDC Industrial Area, Ballabgarh - 121004, Faridabad, INDIA.

Hereby declare and take responsibility to ensure that the following product:

S. No.	Product Description	Medical Device Class	Polymed Reference codes
01	POLYMED High Pressure Extension Line for Photosensitive drugs 150 cm (OD-3.0 mm x ID-1.0 mm)	IIa	13261
02	Polyflo with 40cm tube with Latex free "Y" injection port with fixed luer lock	IIa	13101
03	Polyway Pro (Lipid Resistant) with Paper pack	IIa	13024
04	Polyway pro with DEHP free PVC extension tube (25 cm) White handle	IIa	13051

Comply with the product standards/ requirements and, meet the essential requirements according to Annexure- I of the Council Directive 93/42/EEC of 14th June 1993 as amended by 2007/47/EC concerning medical devices.

Conformity Assessment Procedure was carried out according to Annexure - II excluding section 4 of the MDD and is certified by the following Notified Body.

Name, Address & No.

: TÜV SÜD Product Service GmbH,
Ridlerstraße 65, 80339, Munich, Germany
Notified Body Number 0123,

CE Certificate No.

: G1 041938 0007

Valid Up to

: 26.05.2024

European Authorized Representative Address

: OBELIS S.A.
Boulevard Général Wahis 53,
B-1030, Brussels, Belgium,
mail@obelis.net


RD Sharma

GM – CQRA & PRRC

On behalf of POLY MEDICURE LTD. Faridabad

Poly Medicure Limited

Plot No.104-105, Sector-59, HSIIDC Industrial Area,
Ballabgarh, Faridabad - 121004, Haryana (INDIA)
T: +91-129-3355070, 4287000, F: +91-129-2307007, 2309102
E: info@polymedicure.com W: polymedicure.com



23 August 2023

EC DECLARATION OF CONFORMITY

We Poly Medicure Limited, Plot No. 104-105, Sector-59, HSIIDC Industrial Area, Ballabgarh - 121004, Faridabad, INDIA.

Hereby declare and take responsibility to ensure that the following product:

S. No.	Product Description	Medical Device Class	Customer Ref. code
1	IV Infusion Set (air vent), 57mm drip chamber (DEHP Free), Flow Regulator, Blue Click Clamp, Rotating Luer Lock, MLL Cap, DEHP free Tube-150cm-Blister Pack	IIa	14106

Comply with the product standards/ requirements and, meet the essential requirements according to Annexure- I of the Council Directive 93/42/EEC of 14th June 1993 as amended by 2007/47/EC concerning medical devices.

Conformity Assessment Procedure was carried out according to Annexure - II excluding section 4 of the MDD and is certified by the following Notified Body.

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CE Certificate No.

Valid Upto

: G1 041938 0007

: 26.05.2024

European Authorized Representative Address

: OBELIS S.A.
Boulevard Général Wahis 53,
B-1030, Brussels, Belgium,
mail@obelis.net

SS Rawat

Head - QA

On behalf of POLY MEDICURE LTD. Faridabad