STATEMENT

We, **Global Medikit Limited** having a registered office at 3.Dr.G.C Narang Marg, Delhi-110007, Indiaassign **SRL Sanmedico** having a registered office at A. Corobceanu street 7A, apt. 9, Chișinău MD-2012, Moldova, as authorized representative in correspondence with the conditions of directive93/42/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Date: 29.06.18

Signature:

Global Medikit Limited

Corporate Identity Number : U33119DL2001PLC110470

3, Dr. G. C. Narang Marg, Delhi - 110007 (INDIA) • Tel : +91-11-27662182 / 85 / 89 • Email : domestic@globalmedikit.in • Website : www.globalmedikit.in

Works : Khasra No. 323, (MI) Camp Road, Selaqui, Dehradun - 248197 (UTTRAKHAND)

Digitally signed by Rodnițchii Andrei
Date: 2019.03.21 12:14:02 EET
Reason: MoldSign Signature
Location: Moldova

EC DECLARATION OF CONFORMITY

According to section 2 of Annexure-V of the MDD 93/42/EEC concerning Medical Devices; we are:

Name of Manufacturer : Global Medikit Limited

Country of origin	:	India
Address / Tel / Fax	:	3, Dr. G. C. Narang Marg, New Delhi, India -110007 Ph No. +91-11-27667888
Facility Address	:	Khasra No. 323 (MI), Central Hope Town, CAMP Road; Selaqui Dehradun (Uttrakhand) India.

PRODUCT LIST

- ***Please refer to the attached Annex-A to Declaration of Conformity***

Hereby declare under our own responsibility that the abovementioned products:

- Meet the provisions of the Council Directive 93/42/EC and the essential requirements which apply to them.
- The above mentioned devices have been classified as class III devices according to rule 6 & 7.
- This declaration is supported by the Quality Management System certification ISO 13485:2003 / NS - EN ISO 13485:2012, Certificate No. 248894 -2017-AQ-IND-NA-PS issued by DNV GL NEMKO PRESAFE AS - Veritasveien 3, N-1363 Høvik, Norway.
- This declaration is based on the conformity assessment of products to the requirements of Annex II according to the EC Conformity Certificate No. 247730 -2017- CE-IND-NA-PS issued by DNV GL NEMKO PRESAFE AS - Veritasveien 3, N-1363 Høvik, Norway.
- Notified Body No. : 2460.
- That the product comply all applicable harmonized standard ISO 9001:2008 / EN ISO 13485:2012; EN ISO 14971:2012; EN ISO 11135: 2014; EN ISO 10993-1:2009, EN ISO 15223-1:2016, EN ISO 11737-1: 2006, EN ISO 11737-2:2009 and product Standard .
- The Product is manufactured according to Good Manufacturing Practices.

Issue place: Dehradun

GLOBAL MEDIKIT LTD. SELAQUI DEHRADUN

Date: 30/11/2017

Samar Keshari Jena
[Assistant Manager QA]

European Authorized Representative: Mr. Gideon ELKAYAM (CEO)

Registered Address:

Obelis s.a.
Bd. Général Wahis 53, B-1030 Brussels, Belgium
Phone: 32.2.732.59.54
Fax: 32.2.732.60.03
E-mail: mail@obelis.net

Valid until: This declaration is valid until further notice.

Annex A* – List of devices(CLASS III)

No.	Commercial name of Device	Generic Device Name and model	Class
1.	Epidural Mini Pack	Epidural Kit comprises Epidrual catheter, LOR Syringe, Epidural Needle & Liquid Filter	III
2	Glospine	Spinal needle (Quincke Bevel & Pencil Point)	III
3	Glocent	Central Venous Catheter – Single Lumen (catheter through catheter technique)	III
4	Acent-1,2& 3	Central venous catheter- Single, Double, Triple Lumen (Seldinger Technique)	III

Name of the Manufacturer

GLOBAL MEDIKIT LIMITED

GLOBAL MEDIKIT LTD. SELAQUI DEHRADUN

Name and Position of the Signatory: Samar Keshari Jena [Assistant Manager QA]

Date: 30.11.2017

Stamp:

EC DECLARATION OF CONFORMITY

According to section 2 of Annexure-V of the MDD 93/42/EEC concerning Medical Devices; we are;

Name of Manufacturer : Global Medikit Limited

Country of origin	:	India
Address / Tel / Fax	:	3, Dr. G. C. Narang Marg, New Delhi, India -110007 Ph No. +91-11-27667888
Facility Address	:	Khasra No. 323 (MI), Central Hope Town, CAMP Road; Selaqui Dehradun (Uttrakhand) India.

PRODUCT LIST

- ***Please refer to the attached Annex-A to Declaration of Conformity***

Hereby declare under our own responsibility that the abovementioned products:

- Meet the provisions of the Council Directive 93/42/EC and the essential requirements which apply to them.
- The above mentioned devices have been classified as class IIa, IIb & Is, devices according to rule 1, 2, 6 & 7.
- This declaration is supported by the Quality Management System certification ISO 13485:2003 / NS - EN ISO 13485:2012, Certificate No. 248894 -2017-AQ-IND-NA-PS issued by DNV GL NEMKO PRESAFE AS - Veritasveien 3, N-1363 Høvik, Norway.
- This declaration is based on the conformity assessment of products to the requirements of Annex II according to the EC Conformity Certificate No. 216144-2017- CE-IND-NA-PS issued by DNV GL NEMKO PRESAFE AS - Veritasveien 3, N-1363 Høvik, Norway.
- Notified Body No. : 2460.
- That the product comply all applicable harmonized standard ISO 9001:2008 / EN ISO 13485:2012; EN ISO 14971:2012; EN ISO 11135: 2014; EN ISO 10993-1:2009, EN ISO 15223-1:2016, EN ISO 11737-1: 2006, EN ISO 11737-2:2009 and product Standard .
- The Product is manufactured according to Good Manufacturing Practices.

Issue place: Dehradun

GLOBAL MEDIKIT LTD. SELAQUI DEHRADUN

Samar Keshari Jena
[Assistant Manager QA]

Date: 30/11/2017

European Authorized Representative: Mr. Gideon ELKAYAM (CEO)

Registered Address:

Obelis s.a.
Bd. Général Wahis 53, B-1030 Brussels, Belgium
Phone: 32.2.732.59.54
Fax: 32.2.732.60.03
E-mail: mail@obelis.net

Valid until: This declaration is valid until further notice.

Annex A* – List of devices(CLASS I,IIa&IIb)

No.	Commercial name of Device	Generic Device Name and model	Class
1	Glomax	Tracheostomy Tube	IIb
2	Heamodialysis Catheter	Heamodialysis Catheter Single ,Double, Triple Lumen Central Venous Catheter (Seldinger technique)	IIa
3	Glodrip	I .V. Infusion Set,	IIa
4	Glodrip Alpha	I .V. Infusion Set with Airvent	IIa
5	Glopreg	I. V Fluid Infusion Set with Flow regulator	IIa
6	Glomic Alpha	Microdrip I. V infusion set with built in Airvent	IIa
7	Gloflovi	I .V. Infusion Set with Airvent and Y-Site	IIa
8	Gloryle	Ryle's Tube	IIa
9	Glofant	Infant Feeding Tube	IIa
10	Glonel	Nelaton Catheter	IIa
11	Glolev	Stomach Tube	IIa
12	Glosuc	Suction Catheter	IIa
13	Gloease	Foley's Catheter	IIa
14	Glokot	Malecot Catheter	IIa
15	Gloyan	Yankauer handle with and without connecting tube	IIa
16	Glofab	Laryngeal Mask Airway	IIa
17	Gloflex	Three way Stop Cock	IIa
18	Glomanifold	Stopcock manifold	IIa
19	Gloflexo	Extension Lines with an Integrated three way stopcock	IIa
20	Globob	Blood Administration Set	IIa
21	Glovols	Measure Volume Burette Fluid Infusion Set	IIa
22	Gloalpha	IV Catheter without Injection Valve & without wings	IIa
23	Glocan	IV Catheter without Injection Valve & with wings	IIa
24	Gloflon	IV Catheter with Injection Valve & with wings	IIa
25	Glocan Alpha	IV Catheter without Injection Valve & without wings	IIa
26	Glocath	IV Catheter with Integrated 3-Way stopcock	IIa

27	Gloneo	IV Catheter for Neonates	IIa
28	Glofancie	IV Catheter for Neonates	IIa
29	Gloveins	Extension Line with male and female ends	IIa
30	Gloveins Alpha	High Pressure Extension Line	IIa
31	Gloeal	Endotracheal Tube (Plain)	IIa
32	Gloeal Alpha	Endotracheal Tube (cuffed)	IIa
33	Glomask	Oxygen Mask (Adult, pediatric)	IIa
34	Glowin	Twin Bore Nasal Oxygen Set (Adult, Pediatric)	IIa
35	Gloreg	IV Flow Regulator	IIa
36	Gloex	Mucous Extractor	IIa
37	Glodrain	Wound Drainage Set	IIa
38	Glouro	Urine Bag	Is
39	Glometer	Urine Meter	Is
40	Glonutri	Enteral Feeding Bag	Is
41	Gloway	Guedel Airway (Oropharyngeal Airway)	Is
42	Luer Cap	Luer Cap	Is
43	Injection Stopper	Injection Stopper/NRV	Is
44	Glofin	A V Fistula Needle (With/Without Safety)	IIa
45	Glocic	Thoracic Drainage Catheter	IIa
46	Gloneb	Nebulizer Kit	IIa
47	Fabia	Percutaneous Sheath introducer Set	IIa

Name of the Manufacturer

GLOBAL MEDIKIT LIMITED

GLOBAL MEDIKIT LTD. SELAQUI DEHRADUN

Name and Position of the Signatory: Samar Keshari Jena [Assistant Manager QA]

Date: 30.11.2017

Stamp:

EC Certificate
Full Quality Assurance System

A DNV GL & NEMKO COMPANY

Certificate No.: **247730-2017-CE-IND-NA-PS**

Project No.: **PRJC-558191-2017-MSL-IND**

Valid Until: **14 November 2022**

This is to certify that the quality system of:

Global Medikit Limited
Khasra No. 323 (MI), Camp Road
Selaqui 248 197, Dehradun
Uttarakhand, India

For design, production and final product inspection/testing of:

Disposable Medical Devices

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.1.a and Annex II (Module H1) of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 22 November 2017

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Cathrine Wisbech

Cathrine Wisbech

The Certificate has been digitally signed
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC Certificate
Full Quality Assurance System

Certificate No.: **247730-2017-CE-IND-NA-PS**
Project No.: **PRJC-558191-2017-MSL-IND**
Valid Until: **14 November 2022**

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	2017-11-14

Products covered by this Certificate:

Product Name	Product Model/Variant	Class
Epidural Mini Pack	Size – 16G, 18G	III*
Spinal Needle	Quincke Bevel & Pencil Point Size:18G,19G,20G,21G,22G,23G,24G,25G,26G,27G	III*
Central Venous Catheter	Single Lumen Central Venous Catheter (Catheter through Catheter technique) Single ,Double, Triple Lumen Central Venous Catheter (Seldinger technique)	III*

* Design assessment is covered by a separate EC-Design Examination Certificate No.: 216145-2017-CE-IND-NA-PS (Spinal Needle), 216146-2017-CE-IND-NA-PS (Epidural Mini Pack) and 216147-2017-CE-IND-NA-PS (Central Venous Catheter)

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Global Medikit Limited	Works: Khasra No.323 (MI), Camp Road, Selaqui 248 197 Dehradun Uttarakhand, India Regd Office: 3, Dr. G.C. Narang Marg, Delhi 110007, India

EU Representative

Obelis s.a., Brussels, Belgium

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
247730-2017-CE-IND-NA-PS	PRJC-558191-2017-MSL-IND	14 November 2022

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
216144-2017-CE-IND-NA-PS Rev. 0.0	PRJC-558191-2017-MSL-IND	09 October 2022

This is to certify that the quality system of:

Global Medikit Limited
Khasra No.323 (MI), Camp Road, Selaqui
248 197 Dehradun, Uttarakhand
India

For design, production and final product inspection/testing of:

Disposable Medical Devices

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H2) of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 09 October 2017

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Tone Kolpus

Tone Kolpus

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC Certificate
Full Quality Assurance System

Certificate No.: 216144-2017-CE-IND-NA-PS Rev. 0.0
Project No.: PRJC-558191-2017-MSL-IND
Valid Until: 9 October 2022

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	2017-10-09

Products covered by this Certificate:

Product Description	Product Name	Class
Tracheostomy Tube	Size: 2.0 to 11.0	IIb
Heamodialysis Catheter	Single ,Double, Triple Lumen Central Venous Catheter (Seldinger technique)	IIa
I.V Sets	I .V. Infusion Set, I .V. Infusion Set with Airvent, Microdrip infusion set with built in Airvent, I.V. Set With Flow Regulator, I .V. Infusion Set with Airvent and Y-Site	IIa
Ryle's Tube	Size(FG):8,10,12,14,16,18,20	IIa
Infant Feeding Tube	Size(FG):4,5,6,8,10,12,14,16,18	IIa
Nelaton Catheter	Size(FG):6,8,10,12,14,16,18,20	IIa
Stomach Tube	Size(FG):8,10,12,14,16,18,20,22, 24	IIa
Suction Catheter	Size(FG):6, 8,10,12,14,16,18,20, 22, 24	IIa
Foley's Catheter	Latex Foley Catheter (Two Way/ Three Way) Silicone Foley Catheter (Two Way/ Three Way)	IIa
Malecot Catheter	Size:8Fr to 42Fr	IIa
Yankauer handle with and without connecting tube	Crown tip, Plain tip	IIa
Laryngeal Mask Airway	Size: 1 to 5	IIa
Stop Cock / Stopcock manifold	3-way stop Cock (Plain & Lipid Resistant), 3-way stop Cock (Plain & Lipid Resistant) With	IIa

	extension tube, 2 Way,3 Way,4 Way, Stopcock in line (Plain & Lipid Resistant)	
Blood Administration Set	Vented /Non-Vented	IIa
Measure Volume Burette Fluid Infusion Set	100ml,110ml,150ml	IIa
I.V. Catheter	IV Catheter without injection valve & wings, IV Catheter without injection valve & with wings IV Catheter with injection valve & with wings IV Catheter with integrated 3 way stop cock IV Catheter for Infants and Neonates IV Catheter for Neonates Safety IV Catheter with injection valve and wings	IIa
Extension Set/Tube	Extension Line With male and female ends (Single Lumen, Double Lumen, Triple Lumen), High Pressure Extension Line With male and female Ends	IIa
Endotracheal Tube	Endotracheal Tube with Cuffed Endotracheal Tube without Cuffed	IIa
Oxygen Mask & Twin Bore Set	Oxygen Mask with tubing and nose clip (Adult,Pediatric) Twin Bore Nasal Oxygen Set (Adult,Pediatric)	IIa
IV Flow Regulator	5 – 300ml/h	IIa
Mucous Extractor	8FG, 10FG,12FG,14FG,	IIa
Wound Drainage Set	6 FG TO 18 FG	IIa
Urine Bag	Adult, Paediatric, Legbag	Is
Urine Meter	Urine Collection Bag With Measured Volume Meter	Is
Enteral Feeding Bag		Is
Guedel Airway (Oropharyngeal Airway)	Size: 000,00,0,1,1.5,2,3,4,5,6	Is
Luer Cap		Is

Injection Stopper/NRV		Is
A V Fistula Needle (With/Without Safety)	15G, 16G, 17G	IIa
Thoracic Drainage Catheter	Straight, Curved with/without Trocar	IIa
Nebulizer Kit	Adult, Pediatric	IIa
Percutaneous Sheath Introducer Set	Size(Fr): 5,6,7,8	Iia

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Global Medikit Limited	Works: Khasra No.323 (MI), Camp Road, Selaqui, 248 197 Dehradun, Uttarakhand, India Regd Office: 3, Dr.G.C. Narang Marg, Delhi, 110007, India

EU Representative

Obelis s.a., Brussels, Belgium

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

Management System Certificate

A DNV GL & NEMKO COMPANY

Certificate No.:	Project No.:	Initial Certification Date:	Valid Until:
259056-2018-AQ-IND-NA-PS Rev. 0.0	PRJC-558191-2017-MSL-IND	08 May 2009	08 May 2021

This is to certify that the management system of:

Global Medikit Limited

Unit 1: Khasra no. 323 (MI), Central Hope Town, Camp Road, Selaqui, Dehradun, Uttarakhand, India -248197

Unit 2: Khasra no. 323 (MI), Central Hope Town, Camp Road, Selaqui, Dehradun, Uttarakhand, India -248197

Complies with the requirements of:

ISO 13485:2016 / NS-EN ISO 13485:2016

The Certificate is valid for the following scope:

Unit I: Design, development, manufacture, sales & distribution of sterile / non-sterile single use medical devices used for injection, infusion, blood transfusion, dialysis, anesthesia, general surgery & wound drainage, critical care, respiratory care, urology, gastro enterology, emergency and intensive care.
Unit II: Manufacture of non-sterile Stainless Steel Needles and Tubings for medical devices.

Place and Date:
Høvik, 17 April 2018

NORWEGIAN ACCREDITATION
MSYS 018

For
DNV GL NEMKO PRESAFE AS

Eugenie Winger Husebye

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info