



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 (Uttarakhand) 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

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
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Valid until: This declaration is valid until further notice.

Global Medikit Limited

Corporate Identity Number : U33119DL2001PLC110470

3, Dr. G. C. Narang Marg, Delhi - 110007 (INDIA) • Tel : +91-11-27662182 / 88 / 89 • Email : domestic@globalmedikit.in • Website : www.globalmedikit.in
Works : Khasra No. 323, (MI) Camp Road, Selaqui, Dehradun - 248197 (UTTARAKHAND)



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 Epidural 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



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

Date: 30.11.2017

Stamp:



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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.

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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	Glopre	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

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27	Gloneo	IV Catheter for Neonates	Ila
28	Glofancie	IV Catheter for Neonates	Ila
29	Gloveins	Extension Line with male and female ends	Ila
30	Gloveins Alpha	High Pressure Extension Line	Ila
31	Gloal	Endotracheal Tube (Plain)	Ila
32	Gloal Alpha	Endotracheal Tube (cuffed)	Ila
33	Glomask	Oxygen Mask (Adult, pediatric)	Ila
34	Glowin	Twin Bore Nasal Oxygen Set (Adult, Pediatric)	Ila
35	Gloreg	IV Flow Regulator	Ila
36	Gloex	Mucous Extractor	Ila
37	Glodrain	Wound Drainage Set	Ila
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)	Ila
45	Glocic	Thoracic Drainage Catheter	Ila
46	Gloneb	Nebulizer Kit	Ila
47	Fabia	Percutaneous Sheath introducer Set	Ila

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

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