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: **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.

Digitally signed by Goreacii Tatiana
Date: 2020.07.09 11:30:45 EEST
Reason: MoldSign Signature
Location: Moldova

REPUBLICA MOLDOVA, BULD. CHIȘINĂU, PENTRU CONTRACTE ȘI FACTURI, "SANMEDICO" S.R.L., IDNO 1003602008154, SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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.

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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

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	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

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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

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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