EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
11188-2017-CE-IND-NA-PS Rev. 0.0	**PRJC-102278-2008-PRC-IND**	**24 August 2020**

This is to certify that the quality system of:

Poly Medicure Limited
UNIT III: Plot No. 17, Sector – 3,
Integrated Industrial Estate,
SIDCUL, Haridwar – 249 403, Uttarakhand, India

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

Sterile 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, 29 September 2017

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Alessandra Rinna

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	Supersedes DNVGL (NB 0434) Certificate no: 7047-2015-CE-IND-NA 0.0 following transfer to notified body functions to DNV GL Nemko Presafe AS (NB 2460)	2017-09-29

Products covered by this Certificate:

Product Description	Product	Class
Infusion:		
IV Cannula with/without Safety Features	14G, 16G, 17G, 18G, 20G, 22G, 24G, 26G	IIa
IV Administration Set	Vented/Non-Vented with/without Flow Regulator, 3 Way Stop Cock, Micro Drip, 0.2-micron Filter, Double Chamber and Needle Free Y Set, Auto Fusion & Photo Fusion	IIa
Polyvol Burette Set	100ml, 110ml, 150ml	IIa
Flow Regulators	5 -250 ml/hr	IIa
Luer Locks		IIa
Stylet (Obturator)	14G, 16G, 17G, 18G, 20G, 22G	IIa
CVP Manometer		IIa
Extension Tubes (Multi Lumen)	Low/High Pressure, Coiled, PVC Free, with Needle free connector, Braided	IIa
Flow Regulators		IIa
Stop cocks (with and without extension tubing)	2 way, 3 way, 4 way (Non-Lipid / Lipid Resistant /click)	IIa
Transfusion:		
Blood Transfusion Set	Vented / Non Vented	IIa
Luer Adaptors		IIa
Blood Collection Holder & Needle	19G to 25G	IIa
General Surgery:		

Closed Wound Suction Unit	Neovac in 50 ml, Novovac & Polyvac in Size 200ml, 400ml, 600ml, 800ml	IIa
Yankaur Suction Set with/without Handle	210cm, 250cm, 270cm, 300cm	IIa
Thoracic Drainage Catheter	Straight, Curved with/without Trocar	IIa
Redon Drainage Tubes	6FG to 18FG	IIa
Gynaecology:		
Umbilical Cord Clamp		Is
Urology:		
Urine Bag	800ml - 2000ml with/without Top & Bottom Outlet, with Top Outlet & Rod, With T-Type Bottom Outlet & Sampling Port, Leg Bag Set & Paediatric in Size 100ml	Is
Rectal Catheter	18FG to 32FG	Is
Poly Urimeter	With 250ml & 500ml Volume Meter and 2000ml Urine Collection Bag	Is
TUR Set		Is
Female Catheter	6FG to 20FG	IIa
Nelaton Catheter	6FG to 24FG	IIa
Foley Balloon Catheter	Variant – 2 way, 3 way Adult - 12,14,16,18,20,22,24,26,28,30FG with 30ml to 50ml Balloon Capacity Infant – 6 & 8FG with 3ml to 5ml Balloon Capacity Pediatric – 10FG with 3ml to 5ml Balloon Capacity	IIa
Irrigation Set	Single Spike / Double Spike	IIa
Gastroenterology:		
Levins Tube	6FG to 24FG	IIa
Infant Feeding Tube	4FG to 10 FG	IIa
Ryle's Tube	6FG to 24FG	IIa
Stomach Tube	8FG to 24FG	IIa
Umbilical Catheter	4FG to 8FG	IIa
Feeding Bag		IIa
Respiratory:		
Mucus Extractor with/without Bacterial Filter	Adult, Child	IIa
Sterile Bottle caps	Blue and Pink	Is
Anaesthesia:		

Suction Catheter	5FG to 24FG	IIa
Nasal Oxygen Catheter / Cannula	Adult, Paediatric, Neonatal	IIa
Oxygen Catheter	6FG to 16FG	IIa
Guedel Airways	000, 00, 0, 1, 2, 3, 4, 5	IIa
Tracheal Tube	Plain, Cuffed	IIa
Tracheostomy Tubes		IIa
Dialysis:		
Blood Line Set		IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Poly Medicure Limited	**Plot No. 17, Sector – 3, Integrated Industrial Estate, SIDCUL, Haridwar – 249 403, Uttarakhand, India**

EU Representative

OBELIS S.A., Boulevard General Wahis 53, 1030, 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.

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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