



A DNV GL & NEMKO COMPANY

# EC Certificate Full Quality Assurance System

Certificate No.:  
11186-2017-CE-IND-NA-PS Rev. 0.0

Project No.:  
PRJC-102278-2008-PRC-IND

Valid Until:  
24 August 2020

This is to certify that the quality system of:

**Poly Medicure Limited**  
Plot No. 104 - 105 UNIT I: Plot No. 104 – 105, Sector – 59,  
HSIDC Industrial Area, Ballabgarh – 121 004, Faridabad, 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 11.1.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, 29 September 2017



For:  
DNV GL NEMKO PRESAFE AS

**Alessandra Rinna**

The Certificate has been digitally signed.  
See [www.presafe.com/digital\\_signatures](http://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.:  
11186-2017-CE-IND-NA-PS Rev. 0.0

Project No.:  
PRJC-102278-2008-PRC-IND

Valid Until:  
24 August 2020

### 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: 7045-2015-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 |
|---|---|-------|
| <b>Infusion:</b>  |   |       |
| 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   |
| Extension Tubes (Multi lumen)                                     | Low or High Pressure Coiled and PVC Free with and without needle free connector , Braided   | IIa   |
| Luer Locks  |   | IIa   |
| Stylet (Obturator)  | 14G, 16G, 17G, 18G, 20G, 22G  | IIa   |
| CVP Manometer   |   | IIa   |
| Stop cocks (with and without extension tubing)                    | 2 way, 3 way, 4 way (Non Lipid / Lipid Resistant /click)  | IIa   |
| Needleless Swabable Access Site                                   |   | IIa   |
| Scalp vein (Winged Infusion) Set (with / without safety features) | 18 to 27 G  | IIa   |
| Connection Tube   |   | IIa   |
| Insulin Syringes  | U 40, U 100   | IIa   |
| <b>Transfusion:</b>   |   |       |
| Transfusion Pump Set  |   | IIa   |





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|   |   |     |
|---|---|-----|
| Luer Adaptors   |   | IIa |
| Blood bags containing anticoagulant solution with / without safety features | Single, Double, Triple, Quadruple, Penta & Transfer blood bag system, Blood Bag System with Special Filters and with/ without SAGM                        | IIb |
| Blood Collection System with/without Safety Feature                         | 18 to 24 G  | IIa |
| Blood Collection Set with/without Safety Feature                            | 20 to 26 G  | IIa |
| Blood Collection Holder & Needle  | 19G to 25G  | IIa |
| Blood Transfusion Set   | Vented / Non Vented   | IIa |
| <b>General Surgery:</b>   |   |     |
| 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 |
| Abdominal Drainage Set  | 20FG to 36FG  | IIa |
| Under Water Sealed Drainage System  | Poly drain, Polyseal- Adult, Midi & Kid   | IIa |
| High Pressure Vacuum Drainage Bottle  | 200ml, 400ml, 600ml   | Is  |
| <b>Gynaecology:</b>   |   |     |
| Umbilical Cord Clamp  |   | Is  |
| <b>Urology:</b>   |   |     |
| 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  | Two Way & Three Way   | Iia |
| Irrigation Set  | Single Spike / Double Spike   | Iia |





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COMPANY

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| <b><u>Gastroenterology:</u></b>               |  |     |
|---|--|-----|
| 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 |
| <b><u>Respiratory</u></b>                     |  |     |
| Mucus Extractor with/without Bacterial Filter | Adult, Child                             | Iia |
| Sterile Bottle caps                           | Blue and Pink                            | Is  |
| <b><u>Anaesthesia:</u></b>                    |  |     |
| 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 |
| Catheter Mount                                |  | IIa |
| Oxygen Mask with / without Reservoir          | Adult, Paediatric                        | IIa |
| Nebulizer Mask                                | Adult, Paediatric                        | IIa |
| Venturi Mask                                  | Adult, Paediatric                        | IIa |
| <b><u>Dialysis:</u></b>                       |  |     |
| Blood Line Set                                |  | IIa |
| Haemodialysis Catheter                        | Single Lumen, Double Lumen, Triple Lumen | IIa |
| Fistula Needle with / without Safety          | 15G, 16G, 17G                            | IIa |
| Peritoneal Dialysis Administration Set        |  | IIa |
| Peritoneal Dialysis Catheter Kit              |  | IIa |

The complete list of devices is filed with the Notified Body

**Sites covered by this certificate**





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Project No.:  
PRJC-102278-2008-PRC-IND

Valid Until:  
24 August 2020

**Poly Medicure Limited**

**UNIT I: Plot No. 104 -105, HSIDC Industrial  
Area, Ballabhgarh – 121 004, Faridabad, 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.

### 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





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Project No.:  
PRJC-102278-2008-PRC-IND

Valid Until:  
24 August 2020

This is to certify that the quality system of:

**Poly Medicure Limited**  
UNIT II: Plot No. 115 – 116, Sector – 59,  
HSIDC Industrial Area, Ballabhgarh – 121 004, Faridabad, 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, 3 October 2017



For:  
DNV GL NEMKO PRESAFE AS

*Tone Kolpus*

**Tone Kolpus**

The Certificate has been digitally signed.  
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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: 7046-2015-CE-IND-NA 0.0 following transfer to notified body functions to DNV GL Nemko Presafe AS (NB 2460) | 2017-10-03 |

### Products covered by this Certificate:

| Product Description   | Product   | Class |
|---|---|-------|
| <b>Infusion:</b>  |   |       |
| 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   |
| Extension Tubes (Multi lumen)                                     | Low or High Pressure Coiled and PVC Free with and without needle free connector, Braided  | IIa   |
| Luer Locks  |   | IIa   |
| Stylet (Obturator)  | 14G, 16G, 17G, 18G, 20G, 22G  | IIa   |
| CVP Manometer   |   | IIa   |
| Stop cocks (with and without extension tubing)                    | 2 way, 3 way, 4 way (Non-Lipid / Lipid Resistant /click)  | IIa   |
| Needleless Swabable Access Site                                   |   | IIa   |
| Scalp vein (Winged Infusion) Set (with / without safety features) | 18 to 27 G  | IIa   |
| Huber Infusion Set  | 19 G, 20 G, 22 G  | IIa   |
| Femoral Catheter  | Large, Medium, Small  | IIa   |
| Over The Needle (OTN)   |   | IIa   |





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|   |   |     |
|---|---|-----|
| <b><u>Transfusion:</u></b>                          |   |     |
| Transfusion Pump Set                                |   | IIa |
| Luer Adaptors                                       |   | IIa |
| Blood Collection System with/without Safety Feature | 18 G to 24 G  | IIa |
| Blood Collection Set with/without Safety Feature    | 20 G to 26 G  | IIa |
| Blood Transfusion Set                               | Vented / Non-Vented   | IIa |
| Blood Collection Holder & Needle                    | 19G to 25G  | IIa |
| <b><u>General Surgery:</u></b>                      |   |     |
| 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 |
| Abdominal Drainage Set                              | 20FG to 36FG  | IIa |
| Under Water Sealed Drainage System                  | Poly drain, Polyseal- Adult, Midi & Kid   | IIa |
| High Pressure Vacuum Drainage Bottle                | 200ml, 400ml, 600ml   | Is  |
| <b><u>Gynaecology:</u></b>                          |   |     |
| Umbilical Cord Clamp                                |   | Is  |
| <b><u>Urology:</u></b>                              |   |     |
| 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                              | 2 way, 3 way<br>Adult - 12,14,16,18,20,22,24,26,28,30FG with 30ml to 50ml Balloon Capacity<br>Infant - 6 & 8FG with 3ml to 5ml Balloon Capacity<br>Pediatic - 10FG with 3ml to 5ml Balloon Capacity | IIa |







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|   |  |     |
|---|--|-----|
| Irrigation Set                                | Single Spike / Double Spike              | IIa |
| <b><u>Gastroenterology:</u></b>               |  |     |
| 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 |
| <b><u>Respiratory:</u></b>                    |  |     |
| Mucus Extractor with/without Bacterial Filter | Adult, Child                             | IIa |
| Sterile Bottle caps                           | Blue and Pink                            | Is  |
| <b><u>Anaesthesia:</u></b>                    |  |     |
| 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 |
| Catheter Mount                                |  | IIa |
| Oxygen Mask with / without Reservoir          | Adult, Paediatric                        | IIa |
| Nebulizer Mask                                | Adult, Paediatric                        | IIa |
| Venturi Mask                                  | Adult, Paediatric                        | IIa |
| <b><u>Dialysis:</u></b>                       |  |     |
| Blood Line Set                                |  | IIa |
| Haemodialysis Catheter                        | Single Lumen, Double Lumen, Triple Lumen | IIa |
| Fistula Needle with / without Safety          | 15G, 16G, 17G                            | IIa |

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