

EC Certificate Full Quality Assurance System

Certificate No.:
11701-2017-CE-IND-NA-PS Rev. 0.0

Project No.:
PRJC-04089-2007-PRC-IND

Valid Until:
6 January 2023

This is to certify that the quality system of:

La-med Healthcare Pvt. Ltd.
Plot no: 136 Sector 24 Faridabad Haryana 121005 India

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

Sterile Medical Disposable Devices

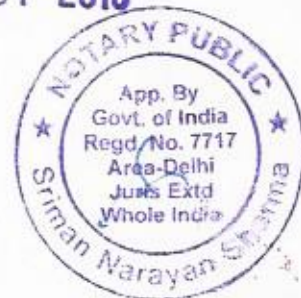
Has been assessed with respect to:

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.

4 OCT 2018



Place and Date:
Høvik, 24 April 2018

For:
DNV GL NEMKO PRESAFE AS



PROD 021
Notified Body No.: 2460

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 | 2018-04-20 |

Products covered by this Certificate:

| Product Description | Product Name | Class |
|---|--|-------|
| Sterile Disposable Medical Devices | | |
| Infusion: | | |
| IV Cannula | With Wings and With Port in Sizes 14, 16, 17, 18, 20, 22, 24, 26G and Brand IV Flon, Novocath, Primaflon, Lamed, Primaflon-S, Cannatech, Primaflo, Primaflo-Pro, Lamed IV Flon Pro, Without Wings and Without Port in Sizes 14, 16, 17, 18, 20, 22, 24, 26G and Brand Primacan alpha, IV Can Alpha, Pen Type IV Cannula in Sizes 14, 16, 17, 18, 20, 22, 24, 26G and Brand Primapen, With Small Wings and Without Port in Sizes 14, 16, 17, 18, 20, 22, 24, 26G and Brand IV Neo Alpha, Prima Neo Alpha, Izzy, IV Neo, IV Can, Primacan, Primaneo, Primacath | Ila |
| IV Cannula with Safety Features | 14G, 16G, 17G, 18G, 20G, 22G, 24G, 26G Brand Primasafe | Ila |
| IV Infusion Set | With or Without Air Vent and 0.2 Micro Filter in Brand Drippy Micro Drip; Drippy, Drippy-V, Drippy-N/V, Drippy Micro-V, Drippy Micor-N/V, Onco Guard, Onco Guard Plus, Drippy Ultra, Drippy Ultra Micro, Transfix-IV, Transfix-V-Prosafe | Ila |
| Measured Volume Burette Set | Drippy Paedia 110 ml; Drippy Paedia 150ml; PET in Brand Drippy Paedia 110 ml; PET in Brand Drippy Paedia 150 ml; PVC Free in Brand Drippy 110 ml; PVC Free in Brand Drippy 150 ml; Drippy Paedia Pro 110ml; Drippy Paedia Pro 150 ml | Ila |

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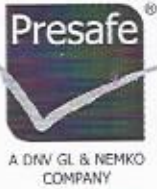
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| | | |
|-----------------------------------|--|-----|
| Flow Regulator /IV flow Regulator | Flow Reg; Drippy Reg; Flow Reg Set; Lamed 5-300 ml/Hr | Ila |
| Infusion Accessories | Heparin Cap/Yellow Stopper- With or without Latex in Brand Lamed Luer Connectors -MLL/FLL for Ext Lines (3/4 mm) Two way spike, Needle Free spike | Ila |
| Three way Stop Cock | Lipid Resistant- Red/White/Blue in Brand Link, Link-3, Link-3KLR, Lamed 3-Way Stopcock, Standard- Red/White/Blue in Brand Link, Link-3, Link-3KLR, Lamed 3-Way Stopcock, | Ila |
| Needle Free Injection Site | Brand Solo Connect, UniConnect, Bi Connect, Tri Connect | Ila |
| Extension Tubing | PVC-Plain/Coiled, Low/High Pressure 5, 10, 25, 50, 75, 100, 125, 150, 200, 250 cm in Brand Link, Link XT, Link PM, Link 3XT, Link CT, Link Micro, Link XT Coiled / Spiral, Link HP, Lamed PVC Free (PE)- Plain/Coiled - 5, 7, 10, 25, 50, 75, 100, 125, 150, 200, 250, 300 cm in Brand Link, Link XT, Link PM, Link 3XT, Link CT, Link Micro, Link XT Coiled / Spiral, Link HP, Lamed | Ila |
| Pressure Monitoring Kit | Single/Double/Triple Transducer kit in Brand Lamed | Ila |
| Transfusion: | | |
| Blood Transfusion Set | With Air Vent; Without Air Vent; Transfix | Ila |
| Urology: | | |
| Urine Collection Bag | Standard: 2000 ml Lamed Premium: 2000 ml Lamed Standard with measuring chamber in Brand U meter: 2000 ml U-Bag Premium with Measuring Chamber: 2000 ml (Brand U-Meter Plus) Paediatric : 100ml U Bag T(With T Type Bottom Outlet) | Is |
| Ureteric Tube | Open & Close End in Brand U-Cath Uretro, Lamed | Ila |
| Female/Urethral Catheter | FG 6, 8, 10, 12, 14, 16, 18, 20, 22, 24 in Brand Lamed, U-90, U-91 | Ila |
| Nelaton Catheter | FG 6, 8, 10, 12, 14, 16, 18, 20, 24FG in Brand Nelto, Lamed | Ila |
| Foley Balloon Catheter | Two Way, FG 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30 | Ila |

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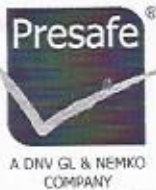
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| | | |
|---|---|-----|
| | Brand U-Cath 2 (Latex) Three way : FG 8, 10, 12, 14, 16, 18, 20, 22 ,24,26,28,30 Brand U-Cath 3 (Latex) Two Way: FG 6, 8, 10, 12, 14, 16, 18, 20, 22 ,24,26,28,30 Brand U-Cath Silico 2 Three way : FG 8, 10, 12, 14, 16, 18, 20, 22 ,24,26,28,30 Brand U-Cath Silico 3 | |
| <u>Gastroenterology:</u> | | |
| Levins Tube | 6, 8, 10, 12, 14, 16, 18, 20, 22 FG in Brand Lamed | Ila |
| Infant Feeding Tube | FG 4, 5, 6, 7, 8, 9, 10 in Brand Infancy, Infancy-PU, Infancy – Silico, Lamed | Ila |
| Ryle's Tube | 6, 8, 10, 12, 14, 16, 18, 20, 20, 22 FG in Brand Rylo-Silico Lamed | Ila |
| Stomach Tube | 6, 8, 10, 12, 14, 16, 18, 20, 22 FG in Brand Lamed | Ila |
| Umbilical Catheter | FG 4, 5, 6, 7, 8, 9, 10 in Brand Lamed | Ila |
| Mucus Extractor | Standard 25 ml in Brand Lamed | Ila |
| Salem Sump Tube | FG 10, 12, 14, 16, 18, 20 FG in Brand Lamed | Ila |
| <u>Anaesthesia & Respiratory</u> | | |
| Suction Catheter | Funnel/Thumb Control/ Finger Tip Control, FG, 5, 6, 8, 10, 12, 14, 16, 18 in Brand Orocath, Orocath PL, Orocath TC, Orocath FT, Lamed | Ila |
| Twin Bore Nasal Oxygen Set | Adult, Child, Infancy Twin O-2 Set in Brand Oxycan, Lamed | Ila |
| Resuscitator (Silicone) | Adult, Paediatric, Infant / Neonates in Brand Lamed | Ila |
| Endotracheal Tube Plain /Reinforced | Plain : 2., 2.5, 3, 3.5, 4, 4.5, 5 in Brand Lamed Cuffed – 5, 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 9.5, 10 in Brand Lamed | Ila |
| Oxygen Mask | Oxygen Mask- Adult, Paediatric, Infant/ Neonate in Brand O2 Mask, Respi-Mask, Oxymask, Lamed | Ila |
| Nebulizer Mask | Nebulizer Mask- Adult, Child, Infancy in Brand NebMask, Neb Mask Plus | Ila |
| Anesthesia Face Mask- | Anesthesia Face Mask- Adult, Child, Infancy in Brand Lamed | Ila |

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Ila



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| Surgery & Drainage | | |
|--|---|-----|
| Yankaur Suction Set | With/without Vent Control/ Crown Tip Handle in Brand Lamed | Ila |
| Umbilical Cord Clamp | Brand Lamed | Is |
| Chest Drainage Catheter/Thoracic Drainage Catheter | Without Trocar –Straight/ Right Angle in size 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 36, 40 in Brand Lamed With Trocar –size FG 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 36, 40 in Brand Lamed | Ila |
| Under Water Seal Drainage System | Standard in Brand Chest-Drain | Ila |
| Abdominal Drainage System | Size FG 16, 20, 24, 28, 32, 36 in Brand AB-Drain, Lamed | Ila |
| Corrugated Drainage System | 250x25 mm in Brand Lamed | Ila |
| Close Wound Suction Unit | Bellow Capacity – 50, 600, 800 ml FG- 6, 8, 10, 12, 14, 16, 18, 20, 22, in Brand VAC Set, Kidi Vac Set, Silico Drain | Ila |
| Redon Drain Catheter | FG 6, 8, 10, 12, 14, 16, 18, 20 in Brand Lamed | Ila |

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

| Site Name | Address |
|-----------------------------|---|
| La-med Healthcare Pvt. Ltd. | Plot no: 136 Sector 24 Faridabad Haryana 121005 India |

EU Representative

CMC Medical Devices & Drugs S.L

C/ Horacio Lengo ,N-18,CP 29006,Malaga Spain

Tel: + 34951214054 e-mail: info@cmcmmedicaldevices.com

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A DNV GL & NEMKO COMPANY

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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



04102

ATTESTED

Gur Singh Dharwal
Executive Assistant
PHD Chamber of Commerce and Industry
New Delhi (INDIA)

-4 OCT 2018



CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia / Country: VIỆT NAM / GIẤY TỜ, TÀI LIỆU NÀY / This public document
 2. do Ông (Bà) / has been signed by: ASHOK KUMAR
 3. với chức danh / acting in the capacity of: Cán bộ Lãnh sự
 4. và con dấu của / bears the seal/stamp of: Bộ Ngoại giao Ấn Độ

được chứng nhận / hợp pháp hóa lãnh sự / Certified

5. tại / at: Niu Đê-ri / the / 6. ngày / 16 / 10 / 2018
 7. cơ quan cấp / by: Đại sứ quán Việt Nam tại Ấn Độ
 8. Số / 2442.3 / 18 / ÁHPH
 Ký tên và đóng dấu / Signature and seal/stamp

TL ĐẠI SỨ / FOR THE AMBASSADOR
Bí thư thứ ba / Third Secretary

Nguyễn Sĩ Dũng



123417
 số No. / दिनांक Date: 16 OCT 2018
 वाणिज्य मंडल में सहायक सचिव उप सचिव/सचिव के हस्ताक्षर प्रत्यक्ष किए जाते हैं।
 The Signature of Asstt. Secretary/Dy. Secretary/Secretary of Chamber of Commerce Attested.
 विदेश मंत्रालय इन वसाधेय के किसी भी विषय वस्तु की जिम्मेदारी नहीं लेता।
 Ministry of External Affairs accepts no responsibility for the contents of this document.



(अशोक कुमार)
 (ASHOK KUMAR)
 उपपुत्र सहायक (सत्यापन)
 Section Officer (Attestation)
 टी. पी. डी. 2भाग / C.P.V. Division
 विदेश मंत्रालय नई दिल्ली
 Ministry of External Affairs, New Delhi