



DNV BUSINESS ASSURANCE

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 179017-2015-CE-IND-NA

This Certificate consists of 6 pages

This is to certify that the Quality Management System of

Lifeline Services Pvt. Ltd.

A-47, Sector-8, Noida – 201 301, Gautam Budh Nagar, Uttar Pradesh, 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 H) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date:

Høvik, 29 September 2015

This Certificate is valid until:

29 September 2020

For DNV GL BUSINESS ASSURANCE
NORWAY AS



Mariann Jeremiassen
Certification Manager

Notified Body No.:
0434

Aud Løken Eiklid
Technical Reviewer

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info

Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.

If any person suffers loss or damage which is proved to have been caused by any negligent act or omission of Det Norske Veritas, then Det Norske Veritas shall pay compensation to such person for his proved direct loss or damage. However, the compensation shall not exceed an amount equal to ten times the fee charged for the service in question, provided that the maximum compensation shall never exceed USD 300.000. In this provision "Det Norske Veritas" shall mean the Foundation Det Norske Veritas as well as all its subsidiaries, directors, officers, employees, agents and any other acting on behalf of Det Norske Veritas.



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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as 'Forskrift for Medisinsk Utstyr' by the Norwegian Ministry of Health and Care Services.

Certificate history

Revision	Description	Issue Date
	Original certificate	2015-09-15

Products covered by this Certificate

Product Description	Product	Class
For Anaesthesia Procedure		
Ventilator Circuit	Variant-Adult, Paediatric, Infant (Without water trapper, with 1 water trapper, with 2 water trapper, Expandable, Expandable with HME Filter, heated vial, non-heated vial, Expandable with HME Filter & catheter mount, without water trapper with CO ₂ port)	IIa
Catheter Mount	Variant- Plain, expendable	IIa
Bain Circuit	Variant- Adult	IIa
J R Circuit (Jackson Rees Circuit)	Variant- Paediatric	IIa
Pressure Monitoring Kit & Pressure Monitoring Line	Variant- Single Dome and Double Dome Variant-Male to Male, Male to Female Size- 10,25,50,100,150,200cm Colour- Red, Blue, Yellow, Clear	IIa
CVP (Central Venous Pressure) Manometer	Variant- With Y site, without Y site Size- Standard	IIa
Suction Catheter	Variant- Plain, with thumb control Size- 5,6,8,10,12,14,16,18,20,22,24 FG	IIa
E.T. Tube (Endotracheal Tube)	Variant- Plain, with cuff and Size- 2,2.5,3,3.5,4,4.5,5, 5.5, 6,6.5,7,7.5,8,8.5,9,9.5,10.0 mm	IIa
Resuscitation Bag	Variant- Adult, Paediatric , Infant	IIa
Lung Exerciser	Variant- 3 ball, 1 ball	Is
Rebreathing Bag	Variant- Black, Green Size- 0.5,1,1.5,2,3,4	IIa
Anaesthesia Face Mask	Variant - Adult, Paediatric – Black, Silicon Size- 0,1,2,3,4,5	IIa



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Twin Oxygen Set	Variant- Adult, Paediatric, Neonatal	IIa
Oxygen Mask/Venturi Mask/ Nebulizer Mask	Variant- Adult, Paediatric, Infant	IIa
3-Way Stop Cock with/without Extension Line and with/without Needle Free Valve	Variant- Non Lipid Resistant, Lipid Resistant for Low/High Pressure in Sizes - 10,15, 25,50,100,150,200 cm	IIa
Guedal Airways	Size- 000,00,0,1,2,3,4,5	IIa
HME Filter	Variant- Adult, paediatric, Infant	IIa
For Gynaecology Procedure		
Umbilical Catheter	Size-3,5,5,6,8FG	IIa
Karman/M.T.P. Cannula	Size- 4,5,6,7,8,9,10,11,12FG	IIa
Umbilical Cord Clamp	Variant- Open-able, Lockable	Is
Silicon Venteuse Cup	Size- 50,60,70MM	IIa
For Cardiology Procedure		
High Pressure Monitoring Line	Variant- Male to Male, Male to Female Braided./ Non-Braided in Size- 20,50,100,120,150,200 cm	IIa
Connectors	Variant- Straight with/without luer lock Size - 1/4" x 1/4"; 3/8" x 3/8"; 1/2" x 1/2"; 1/2" x 1/4" 1/2"x 3/8"; 3/8" x 1/4"; 3/8"x 1/4"; 1/4" x 3/16", 3/16" x3 /16" Y Connector with/without luer lock Size - [1/2" x 1/4 x 1/4"; 3/8" x 1/4"x 1/4"; 1/2" x 1/2"x 1/4"; 3/8" x 3/8" x 1/4"; 2" x 3/8"x 1/4"; 1/4" x 1/4"x 1/4"; 3/8" x 3/8" x 3/8"; 1/2"x1/2"x1/2"; 1/2" x 3/8" x 3/8"; 1/2" x 1/2" x 3/8"; 3/16"x3/16"x3/16"	IIa
Manifold	Variant- 2 Way, 3 Way, 4 way, 5 way Right/Left Handed ON and/or OFF with/without Rotating Adapter for 250 PSI and 500 PSI	IIa
B.C.D. on line	Variant- Adult, Paediatric, Infant	IIa
Rigid Suction Devices (Sucker)	Variant- Adult, Paediatric, Mini	IIa
Cardioplegia Adapter	Variant- 2 way and 4 way	IIa
Hemoconcentrator	Variant- Adult, Paediatric, Infant	IIa
Arterial Line Filter	Variant- Adult, Paediatric, Infant	IIa
AV (arterio-venous) Tubing	Size- 1/4"x 1/16", 3/8"x 3/32", 1/2"x 3/32", 3/16"x 3/64", 1/16"x3/16", 1/8"x1/16"	IIa
Cardioplegia Connector	Variant- with luer lock, without luer lock	IIa
Blood Cardioplegia Delivery Set	All Variants	IIa



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Custom Pack-Heart Lung Pack	Variant- Adult, Paediatric, Infant with/without filter	IIa
Haemostasis Valve	Variant- Y-click, Push & pull type, Rotating Type, double rotating type, with tubing, without tubing Size- Plain, 3way	IIa
For General Surgery Procedure		
Yankauer Set	Variant- Plain Tip, Crown Tip, with Filter	IIa
C.D. Catheter	Variant- Straight, Angled with/without Trocar Size- 8,10,12,14,16,18,20,22,24,26,28,30,32,34,36,40 FG	IIa
Disposable Chest Drainage System (C.D. Bottle)	Variant- Adult, Paediatric Size- Single chamber, Double chamber	IIa
Drain-O-Pack	Size- 10, 12, 14, 16, 18 FG	IIa
Mini Drain-O-Pack	Size- 6,8 FG	IIa
Abdominal Drainage Kit	Size- 16, 20,24,28,32,36 FG	IIa
Corrugated Drain Sheet	Size- Standard	IIa
Disposable Hygiene Wear	Caps, Masks, Gowns, Drapes, Shoe Cover in All Sizes	Is
Biopsy Needle	Size- 7,8,13 FG	IIa
Ryle's Tube	Size-6, 8,10,12,14,16,18,20,22,24FG	IIa
Levin's Tube	Size- 6, 8,10,12,14,16,18,20,22,24FG	IIa
Infant Feeding Tube	Size- 4,5,6,7,8,9,10FG	IIa
Infant Mucus Extractor with /without Filter		IIa
For Infusion Procedure		
I.V. (Intravenous) Set,	Variant – Vented/Non vented with/without Air Vent, Y Site, Filter, Luer Lock and Flow Regulator	IIa
M.V. Set (Measured Volume)	Variant- Adult, Paediatric - Plain with/without Y-Site, Luer Lock in Size- 110 ml, 150 ml	IIa
B.T. (Blood Transfusion) Set	Variant - Single chamber with/without filter, Y-site and Luer Lock Double chamber with/without filter, Y-site and Luer Lock	IIa
Haemodialysis Blood Tubing Set	All variants	IIa
I.V. Cannula	Variant- with wings & with injection port, with wing & without injection port, without wing & without injection port, without wing & without Injection port Size - 14, 16, 17, 18, 20, 22, 24, 26 G	IIa
Blood Transfusion Filter	Size- 40 micron	IIa
AV Fistula Needle	Variant- Twin set, Single Size- 15,16,17 G	IIa



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Peritoneal Dialysis Sets & Peritoneal Dialysis Catheter	Variant- Adult, Paediatric, Infant Variant- Adult, Paediatric, Infant	Ia
For Urology Procedure		
Urine Collection Bag & Uro- Measure	Variant- top outlet, bottom outlet, top & bottom outlet Variant- with measuring Cylinder	Is
Foley Balloon Catheter	Variant- 2 way, 3 way Adult - 12,14,16,18,20,22,24FG with 30ml to 50ml Balloon Capacity Infant – 6 & 8 GF with 3ml to 5ml Balloon Capacity Paediatric – 10G with 3ml to 5ml Balloon Capacity	Ia
T.U.R. (Transurethral Resection) Set	All Variants	Ia
Nelaton Catheter	Size- 6,8,10,12,14,16,18,20,22,24FG	Ia
Urethral Catheter	Size- 10,12,14FG	Ia
Male Catheter	Size- 20, 25, 30, 35 mm	Ia

The complete list of devices is filed with the Notified Body.

Sites covered by this certificate

Site Name	Address
Lifeline Services Pvt. Ltd.	A-47, Sector-8, Noida – 201 301, Gautam Budh Nagar, Uttar Pradesh, India

EU Representative:

Med Devices Lifesciences Pvt. Ltd., The Black Church, St. Mary's Place, Dublin 7, Ireland,
 Tel.: +353 766801106, email: info@meddevices.net



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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 the local DNV Office of any intended updating of the quality system and DNV 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 DNV 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 DNV.

END OF CERTIFICATE