



# DET NORSKE VERITAS

## FULL PRODUCT QUALITY MANAGEMENT CERTIFICATE - EC

Certificate No. 56120-2009-CE-IND-NA Rev. 1.0

This Certificate consists of 7 pages

*This is to certify that the Quality Management System of*

### **Lifeline Systems Private Limited**

A-49, Sector - 8, Noida – 201 301, District Gautam Budh Nagar, Uttar Pradesh, India

*for 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, 19 August 2009

*This Certificate is valid until:*

**19 August 2014**

For DET NORSKE VERITAS AS  
Norway



Notified Body No.:  
0434

Marianne Spæren  
Certification Manager

Jenny Helen Nytn  
Technical Reviewer

**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	2003-10-22
1.0	Recertification	2009-08-19

## Products covered by this Certificate

Product Description	Product Name	Class
I.V. Cannula	Belflon, Life-O-Flon, With/Without Wings <ul style="list-style-type: none"> <li>▪ 14G, 16G, 17G, 18G, 20G, 22G, 24G, 26G, 27G</li> </ul>	IIa
Hypodermic Syringes	<ul style="list-style-type: none"> <li>▪ 1ml, 2ml, 3ml, 5ml, 10ml, 20ml, &amp; 50ml with 20G to 26G Needle</li> <li>▪ 1ml, 2ml, 3ml, 5ml, 10ml, 20ml, &amp; 50ml without Needle</li> </ul>	IIa
Biopsy Needle	<ul style="list-style-type: none"> <li>▪ FG 7, 8, 10</li> </ul>	IIa
Catheter Mount		IIa
Endotracheal Tube	<ul style="list-style-type: none"> <li>▪ Plain (2, 2.5, 3, 3.5, 4, 4.5, 5)</li> <li>▪ Cuffed (5, 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 9.5, 10)</li> </ul>	IIa
Guedel Airways	<ul style="list-style-type: none"> <li>▪ 000, 00, 0, 1, 2, 3, 4, 5</li> </ul>	IIa
Nasal Oxygen Catheter	<ul style="list-style-type: none"> <li>▪ FG 6,8,10,12,14,16</li> </ul>	IIa
Adapters, Connectors, Luer Locks, Safety Caps for General Surgery & Anaesthesia Circuits	<ul style="list-style-type: none"> <li>▪ Straight Connector, Reducer Connector, Straight Connector with Luer Lock, Y Connector, Y Connector with Luer Lock, Female Luer Lock, Male Luer Lock, Dust Cap, Dead Enders, Y Connector Paediatric with/without Port, Y Connector Adult with/ without Port, Water Trapper, Elbow with/without Port, Swivel Connectors, Cuffed Adult, Circuit Cuff Adult/Paediatric, Respiratory Circuit Cuff with/without Cap, Paediatric Cuff Type-2, Elbow with Port, with dead ender or Luer lock</li> </ul>	IIa
Oxygen / Ventur / Nebulizer Mask	<ul style="list-style-type: none"> <li>▪ Adult, Paediatric</li> </ul>	IIa
Suction Catheter	<ul style="list-style-type: none"> <li>▪ With Thumb Control/Finger Tip Control/ Funnel Connector in FG 6, 8, 10, 12, 14, 16, 18</li> </ul>	IIa



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Tracheostomy Tube	<ul style="list-style-type: none"> <li>▪ Plain - FG 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 7.5, 8</li> <li>▪ Cuffed - FG 6, 7, 7.5, 8, 8.5, 9, 9.5, 10</li> </ul>	IIa
Twin Oxygen Set	<ul style="list-style-type: none"> <li>▪ Adult, Paediatric</li> </ul>	IIa
Tuohy Needle	<ul style="list-style-type: none"> <li>▪ FG 17 &amp; 18</li> </ul>	IIa
Oxygen Recovery Kit		IIa
Cardioplegia Delivery System	<ul style="list-style-type: none"> <li>▪ Spiral Type &amp; Tube Type</li> </ul>	IIa
Chest Drainage Catheter	<ul style="list-style-type: none"> <li>▪ Angled &amp; Straight</li> <li>FG 12, 16, 20, 24, 28, 32, 36, 40</li> </ul>	IIa
Disposable Chest Drainage System	<ul style="list-style-type: none"> <li>▪ Adult, Paediatric</li> </ul>	IIa
Catheter	<ul style="list-style-type: none"> <li>▪ Single, Double, Triple Lumen</li> </ul>	IIa
Vessel Cannula	<ul style="list-style-type: none"> <li>▪ With/without One Way Valve</li> </ul>	IIa
Sucker	<ul style="list-style-type: none"> <li>▪ Normal/Mini</li> <li>With/Without Finger Tip Control</li> </ul>	IIa
Thoracic Trocar Catheter	<ul style="list-style-type: none"> <li>▪ FG 16, 20, 24, 28, 32, 36, 40</li> </ul>	IIa
Intra Coastal Drainage System		IIa
Lung Exerciser		IIa
Blood Cardioplegia Delivery System	<ul style="list-style-type: none"> <li>▪ With 2Way / 4Way Adapter</li> </ul>	IIa
Drain-O-Pack	<ul style="list-style-type: none"> <li>▪ Adult, Mini</li> </ul>	IIa
Yankaur Type Handle	<ul style="list-style-type: none"> <li>▪ With / Without Filter</li> </ul>	IIa
Abdominal Drainage System	<ul style="list-style-type: none"> <li>▪ FG 20, 24, 28, 32, 36</li> </ul>	IIa
M.T.P. Cannula	<ul style="list-style-type: none"> <li>▪ 3, 4, 5, 6, 8, 9, 10, 11, 12</li> </ul>	IIa
Silicone Venteuse Cup With Disengaging Level	<ul style="list-style-type: none"> <li>▪ 60mm, 70mm Cup</li> </ul>	IIa
Disposable Suction Bags	<ul style="list-style-type: none"> <li>▪ 1 Litre, 2 Litre</li> </ul>	IIa
Umbilical Catheter	<ul style="list-style-type: none"> <li>▪ FG 3.5, 5, 6, 8</li> </ul>	IIa
Epidural Set	<ul style="list-style-type: none"> <li>▪ FG 17, 18, 19</li> </ul>	IIa



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Blood Transfusion Set		IIa
I.V. Set	<ul style="list-style-type: none"><li>Vented/Non vented with/without Luer Lock</li><li>Microdrip &amp; Rapid Infusion Set</li></ul>	IIa
Feeding Tubes	<ul style="list-style-type: none"><li>FG 5, 6, 7, 8, 9, 10</li></ul>	IIa
Ryles Tube	<ul style="list-style-type: none"><li>FG 8, 10, 12, 14, 16, 18, 20</li></ul>	IIa
Liv-O-Flex	<ul style="list-style-type: none"><li>8mm &amp; 10mm</li></ul>	IIa
Foley Catheter	<ul style="list-style-type: none"><li>Two Way FG 6, 8, 10, 12, 14, 16, 18, 20, 22, 24 With Balloon Capacity 30ml</li><li>Three Way FG 16, 18, 20, 22, 24 With Balloon Capacity 30ml-50ml</li></ul>	IIa
Measured Volume Burette Set	<ul style="list-style-type: none"><li>110ml, 150ml</li></ul>	IIa
T-Tubes	<ul style="list-style-type: none"><li>FG 10, 12, 14, 16, 18</li></ul>	IIa
Infant Mucous Extractor	<ul style="list-style-type: none"><li>20ml with / without filter</li></ul>	IIa
Levins Tube	<ul style="list-style-type: none"><li>FG 6, 8, 10, 12, 14, 16, 18</li></ul>	IIa
Spike		IIa
Supra Cath		IIa
Manifolds	<ul style="list-style-type: none"><li>2 Core, 3 Core, 4 Core (Right On/Off)</li></ul>	IIa
C.V.P. Manometer		IIa
Life-O-Flow		IIa
Scalp Vein Set	<ul style="list-style-type: none"><li>FG 14, 16, 18, 19, 20, 21, 22, 23, 25, 27</li></ul>	IIa
Blood Donor Set		IIa
Dome	<ul style="list-style-type: none"><li>HP 1295C, HP 1290, P23 ID</li></ul>	IIa
Peritoneal Dialysis Catheter	<ul style="list-style-type: none"><li>Adult, Child</li></ul>	IIa
Peritoneal Dialysis Set		IIa
Blood Tubing Set	<ul style="list-style-type: none"><li>With/Without Fistula Needle</li></ul>	IIa
Male Catheter		IIa



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Nelaton Catheter	▪ FG 6, 8, 10,12,14,16,18,20,22,24	IIa
TUR Set		IIa
Urethral Catheter	▪ FG 10, 14	IIa
Heart Lung Packs	▪ Adult / Paediatric / Neonate (With or Without Arterial Filter)	IIa
Arterial Venous Tubing Set	▪ With or Without Transducer Protector	IIa
Kits	Pressure Monitoring Kits ▪ Single/Double/Triple Disposable Transducers Kits Angio or PTCA Kits ▪ Double/Triple/Quadruple Manifolds PTCA/Cath Lab Kits	IIa
Pressure Monitoring Lines	▪ With Male and Female Luer Locks	IIa
Extension Lines	▪ With Stopcock / With I.V Line / With PT Line	IIa
Guide wire	▪ J Tip & straight	IIa
Respiratory Circuit	▪ Adult / Paediatric With or Without HME Filter , With or Without Water Trap Expandable or Non Expandable Circuits in White & Blue Colo	IIa
Anaesthesia & Critical Care Products	▪ Dialysis Catheters Single/Double/ Triple/ Quadruple Lumen	IIa
Pressure Monitoring Kit / Anaesthesia Accessories	▪ Transducer Domes, Disposable Pressure Transducer, Flush Device (2/3 Ports), Stopcocks, Transducer Interface Cables, Male/Female Port Caps, IV Sets, IV Line Filters, IV Drip Chambers Vented / Non Vented, Clamping Devices (Pinch Clamps / Roller Clamps / Slide Clamps), Luer Connectors (Male/Female)	IIa
Cath Lab Kit Accessories	▪ Manifolds (2/3/4 Core), Control Syringe, Hemostatic Y Connector, Torque Device, Introducer Needle, Spinal Needle, Inflation Device, Introducer Sheath, High Pressure Line, Contrast Media Set, Guide wires	IIa
Heart Lung Pack Accessories	▪ Connectors (Straight / Y) with/without Luer Lock, Step Connector, Arterial Filter with Loop, Arterial Filter (Adult/Paediatric/Infant), BT Filter, Duck Bill Check Valve, Tubing Rolls, Purge Line with/without One Way Valve, Quick Prime Line, Gas Line/ Intervene P1000	IIa



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<p>Respiratory Circuit Accessories</p>	<p>Filters, Isolator Line, Tubing Organizer, Cannula/Catheter</p> <ul style="list-style-type: none"> <li>▪ HME Filter (Adult/Paediatric), Bacterial Viral Filter, Water Trap, Respiratory Tubing Rolls (Adult/Paediatric), Respiratory Cuff Connectors, Respiratory Straight Connectors, Respiratory Elbow Connectors, Respiratory Swivel Connectors, Respiratory Y Connectors (With &amp; Without Port), Bain Circuit, APL Valve for Bain Circuit, Resuscitation Bags, Oxygen Bag for Resuscitator, Re-breathing Bags, Anaesthesia Face Mask (Silicon/Rubber)</li> </ul>	<p>IIa</p>
<p><b>Sterile Disposable Medical Devices</b></p>	<p>Urine Collection Bags - 2000ml          Uromasure          Hourly Urine Measurement Unit          Corrugated Sheets          Disposable Surgical Hygiene Wear          Surgidrape Non Medicated          Umbilical Cord Clamp          Transparent Gloves          Tie Gun          Tie Wraps          Tubing Organiser</p>	<p>Is</p>

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

**Sites covered by this certificate**

Lifeline Systems Pvt. Ltd.

A-49, Sector - 8, Noida – 201 301, District Gautam Budh Nagar, Uttar Pradesh, India

**EU Representative**

ALUNOX Limited, 43, Thuriston Avenue Solihull, West Midlands, B 92 7 NZ, United Kingdom



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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