



CERTIFICATE OF ASSESSMENT - EC

DET NORSKE VERITAS

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

Certificate N°.: 2003-OSL-MDD-0338

This is to certify that the Quality System for the product group:

Disposable Procedure Packs

- defined by manufacturer as Class IIa devices -

Manufactured by

Lifeline Systems Pvt. Ltd.

A 49, Sector VIII, NOIDA 201301, INDIA

complies with the applicable requirements of the Directive.

The quality system for these products has been assessed according to the procedure of conformity assessment described in **Article 11.3.a) and Annex II (excl. section 4)**. Identification of the products covered by this certificate is given in the Appendix.

Limitations:

The manufacturer must inform Det Norske Veritas Certification AS of any plan for substantial changes to the quality system in order to examine whether this Certificate remains valid. Annual Periodical Audits will be held to verify the validity of this Certificate.

Høvik, 22 October 2003

for Det Norske Veritas Certification AS

Valid until: 22 October 2008

Line Gangeskar

*Head of section, Testing, Product and Personnel
Certification*

CE
0434

Eugenie Winger Husebye

Service responsible Medical Devices

This Certificate is valid until the date specified. Any significant changes in the design or construction of the products, the quality system or amendments to the Directive may render this Certificate invalid at an earlier date. The product liability rests with the manufacturer or his representative in accordance with Council Directive 85/374/EEC

**CERTIFICATE OF ASSESSMENT - EC APPENDIX**

Appendix to Certificate No.: 2003-OSL-MDD-0338
Manufacturer: Lifeline Systems Pvt. Ltd.
Product group: Disposable Procedure Packs

The Certificate referred to above covers the following devices:

- **Pressure Monitoring Kit**
 - **Angio Kit**
- **Heart Lung Packs**
- **Pressure Monitoring Lines**
- **Extension Lines**
- **Component Packaging**
- **Respiratory Circuits**

The Complete list of the devices is filed with the Notified Body, ref.: project no. 42034 191

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22 October 2003

Eugenie Winger Husebye

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