EC Design Examination Certificate

Medical Devices Directive 93/42/EEC

*The National Standards Authority of Ireland as a duly designated Notified Body, (identification number **0050**), for the purposes of the European Communities (Medical Devices) Regulations (S.I. No. 252 of 1994)*

HAS EXAMINED THE DESIGN DOSSIER
Submitted by

ALung Technologies Inc

2500 Jane Street,
Suite 1
Pittsburgh
PA 15223-2216
USA

For Product Family

Extracorporeal membrane oxygenator (Hemolung® Respiratory Assist System - Cartridge Kit).

CONCLUSION of EXAMINATION:
Complies with the requirements of Annex II, Section 4 of Directive 93/42/EEC

Registration Number:	**252.844**
Original Approval:	**22 February 2013**
Last Amended on:	**22 February 2013**
Remains valid until:	**21 February 2016**

Signed:

Approved by:
Kevin D. Mullaney
Chief Executive Officer - NSAI Inc.

Approved by:
John O'Dwyer
European manager

CONDITIONS OF VALIDITY:
This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.
Note: Changes which could affect conformity with the essential requirements of Directive 93/42/EEC, or with the conditions prescribed for use of the product must receive further approval from NSAI.
National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.