EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 597923**

Issued To: **ALung Technologies, Inc.**
2500 Jane Street, Suite 1
Pittsburgh
Pennsylvania
15203
USA

In respect of:

Extracorporeal membrane oxygenator named as Hemolung® Respiratory Assist System as a cartridge kit

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Albert Roossien, Regulatory Lead

First Issued: **2013-08-08** Date: **2019-02-04** Expiry Date: **2021-02-21**

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Supplementary Information to CE 597923

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Model:	REF 10000 Hemolung Cartridge Kit – SM IV Configuration
Model:	REF 11000 Hemolung Cartridge Kit – CME IV Pump Configuration
Model:	REF 10002 Hemolung Cartridge with Pre-Connected Tubing (XG4)

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Certificate History

Date	Reference Number	Action
08 August 2013	10141214	Certificate transfer from NSAI. This certificate is traceable to this company's original registration certificate number 252.844, dated 22 February 2013 and issued by NSAI.
09 January 2014	10144606	The addition of model REF 11000 Hemolung Cartridge Kit – CME IV Pump Configuration. The extension of SM IV Pump Configuration to the existing model.
12 July 2014	10148436	Change to DEHP-free material for the to-patient and from-patient tubing sets.
26 November 2014	10149997	Qualification of new source for isocyanate used in Hemolung Cartridge potting material.
17 June 2015	10149596	Accessories removed from the design dossier and documented in a new technical file. Design changes to improve usability.
18 February 2016	10159055	Certificate Renewal.
05 January 2017	10158937	Change of "Indication of Use" in removing the following: "The Hemolung Respiratory Assist System is not indicated for patients needing assistance in weaning from invasive mechanical ventilation, patients with severe asthma, and patients preparing for and following lung transplantation".
Current	8092647	Traceable to NB 0086.

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