

EC Certificate - Full Quality Assurance System

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

No. CE 597921
Issued To: **ALung Technologies, Inc.**
2500 Jane Street, Suite 1
Pittsburgh
Pennsylvania
15203
USA

In respect of:

The design and manufacture of a cardiopulmonary bypass centrifugal pump drive unit, an extracorporeal respiratory assist system with heparin coating as a cartridge kit, accessories for extracorporeal respiratory assist systems, and central venous catheterization kits

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II 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: **2019-02-05**

Expiry Date: **2021-02-21**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:

Service(s) supplied

Healthlink Europe B.V.
De Tweeling 20-22
s-Hertogenbosch 5215 MC
The Netherlands

EU Representative

iuvo BioScience - Erie, LLC
2205 East 33rd Street
Erie
Pennsylvania
16510
USA

ETO Sterilization

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Certificate History

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Date	Reference Number	Action
08 August 2013	7974566	Certificate transfer from NSAI. This certificate is traceable to this company's original registration certificate number 252.838, dated 22 February 2013 and issued by NSAI.
17 June 2015	8193094	Update to certificate scope to include accessories for extracorporeal respiratory assist systems.
14 December 2015	8428802	Certificate renewal. Update of sterilization subcontractor from Ethox International Inc., to iuvo BioScience - Erie, LLC.
Current	8092647	Traceable to NB 0086. Administrative Subcontractor Service wording update from 'Sterilization' to 'ETO Sterilization' for iuvo BioScience LLC, 2205 East 33rd Street, Erie, Pennsylvania, 16510, USA.