EC Certificate Full Quality Assurance System: Certificate US13/82829

The management system of

ProLung Inc.

757 E. South Temple, Suite 150,
Salt Lake City, UT, 84102, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

ProLung System, to aid physicians in the risk stratification of patients for the presence of lung cancer following detection of a pulmonary lesion by computed tomography.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 04 October 2017 until 10 May 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 18 March 2019
Issue 7. Certified since 10 May 2013

Certification is based on reports numbered WW/MW 604441

Authorised by

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