

EC Certificate - Full Quality Assurance System

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

No.**CE 669605**

Issued To:

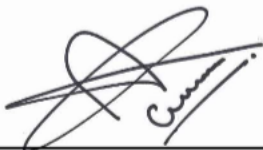
Liger Medical LLC**3300 North Running Creek Way
Building G
Lehi
Utah
84043
USA**

In respect of:

Design and Manufacture of Thermal Ablation Devices.

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: **2017-12-08**Date: **2019-02-14**Expiry Date: **2022-12-07**

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Page 1 of 1

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:

Certificate No: **CE 669605**
Date: **2019-02-14**
Issued To: **Liger Medical LLC**
3300 North Running Creek Way
Building G
Lehi
Utah
84043
USA

Subcontractor:

Service(s) supplied

SMIDGEN
Millhouse, Bleach Rd.
Kilkenny,
Ireland

EU Representative

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 669605**
 Date: **2019-02-14**
 Issued To: **Liger Medical LLC**

**3300 North Running Creek Way
 Building G
 Lehi
 Utah
 84043
 USA**

Date	Reference Number	Action
8 December 2017	8694370	First issue.
Current	8694380	Traceable to NB 0086.

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