

EC Certificate - Full Quality Assurance System

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

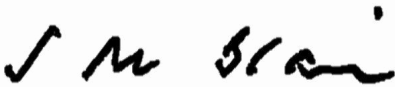
No. CE 650446
Issued To: **Strata Medical Innovations, Inc.**
3706 76th Street
Lubbock
Texas
79423
USA

In respect of:

The design and manufacture of handheld nitrous oxide gas delivery devices, associated mouthpieces and masks, and nitrous oxide gas cylinders for short term analgesia in minimal access surgery.

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 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2017-06-05**

Date: **2017-12-05**

Expiry Date: **2022-06-04**

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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
ARAZY GROUP GmbH European Representative Am Kalkofen 8 61206 Wollstadt Germany	EU Representative
Gourmet Innovations 6727 NW 16th Terrace Fort Lauderdale 33309 USA	Crucial Supplier
LISS Patrongyártó Töltő és Forgalmazó Kft. Carl von Linde út 1. H-9653 Répcelak Hungary	Crucial Supplier

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
5 June 2017	8488340	First Issue.
Current	8813938	Extension to scope to add the masks. Addition of crucial supplier Gourmet Innovations.

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