

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 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 2797):



Albert Roossien, Regulatory Lead

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

Date: **2019-03-21**

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

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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.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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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

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 650446**
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Date	Reference Number	Action
5 June 2017	8488340	First Issue.
5 December 2017	8813938	Extension to scope to add the masks. Addition of crucial supplier Gourmet Innovations.
20 March 2019	9736670	Removal of the nitrous oxide gas cylinders from the scope. Removal of crucial suppliers Gourmet Innovations and LISS Patrongyarto.
Current	8801126	Traceable to NB 0086.

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Page 1 of 1

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