

EC Certificate - Full Quality Assurance System

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

No. CE 599480
Issued To: **Minimus Spine**
12885 Research Blvd, Suite 210A
Austin
Texas
78750
USA

In respect of:

Those aspects of Annex II concerned with securing and maintaining sterile conditions of medical ozone delivery syringes.
Those aspects of Annex II concerned with the metrological requirements of medical ozone generation 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 0086):



Gary Fenton, Global Assurance Director

First Issued: **04 July 2014**

Date: **04 July 2014**

Expiry Date: **03 July 2019**

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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
Emergo Europe Molenstraat 15 2513 BH The Hague Netherlands	EU Representative
NUPAK MEDICAL LIMITED 11849 Starcrest Drive San Antonio Texas 78247 USA	Assembly Packaging
Sterigenics US LLC 5725 West Harold Gatty Drive Salt Lake City Utah 84116 USA	ETO Sterilization

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
04 July 2014	7999300	First issue

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