By Royal Charter

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 599480**
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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