EC Certificate - Full Quality Assurance System

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

No. **CE 654489**

Issued To: **Woven Orthopedic Technologies LLC**
63 E. Center Street
Suite 3A
Manchester
Connecticut
06040
USA

In respect of:

Design and manufacture of spinal screw retention devices and associated instruments.

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: **2018-10-05** Date: **2019-03-11** Expiry Date: **2023-10-04**

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Supplementary Information to CE 654489

Issued To:

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63 E. Center Street
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NBOG Code(s)	Device Name	Intended purpose per IFU
Class IIb		
MD 0202	OGmend™ Sleeve	Fixation enhancement in the spine
Class IIa		
MD 0106	OGmend™ instrument (Inserter)	Instrument to insert OGmend™ implant system device

First Issued: **2018-10-05** Date: **2019-03-11** Expiry Date: **2023-10-04**

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By Royal Charter

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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 654489**
Date:	**2019-03-11**
Issued To:	**Woven Orthopedic Technologies LLC** **63 E. Center Street** **Suite 3A** **Manchester** **Connecticut** **06040** **USA**

Subcontractor:	**Service(s) supplied**
Confluent Medical Technologies Inc 60 Commerce Drive Warwick RI 02886 USA	**Manufacture**
Emergo Europe B.V. Prinsessegracht 20 The Hague 2514 AP The Netherlands	**EU Representative**
FIL.VA SRL Sede Legale Uffici e Stabilmento Via oer Schianno 64-21100 Varese Italy	**Crucial Supplier**

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Subcontractor:	**Service(s) supplied**
Isomedix Operations, Inc. 23 Elizabeth Drive Chester New York 10918 USA	**Gamma Irradiation**
Sequel Special Products 1 Hillside Drive Wolcott Connecticut 06716 USA	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 654489**

Date: **2019-03-11**

Issued To: **Woven Orthopedic Technologies LLC**
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Manchester
Connecticut
06040
USA

Date	Reference Number	Action
05 October 2018	8535386	First issue.
Current	9714365	Traceable to NB 0086.