

# EC Certificate - Full Quality Assurance System

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

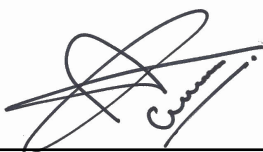
**No.** CE 654489  
**Issued To:** **Woven Orthopedic Technologies LLC**  
**63 E. Center Street**  
**Suite 3A**  
**Manchester**  
**Connecticut**  
**06040**  
**USA**

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**

...making excellence a habit.™

Page 1 of 2

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.

# EC Certificate - Full Quality Assurance System

## Supplementary Information to CE 654489

Issued To:

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

NBOG Code(s)	Device Name	Intended purpose per IFU
<b>Class IIb</b>		
MD 0202	OGmend™ Sleeve	Fixation enhancement in the spine
<b>Class IIa</b>		
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**

...making excellence a habit.™

Page 2 of 2

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.

# EC Certificate - Full Quality Assurance System

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**

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

...making excellence a habit.™

# EC Certificate - Full Quality Assurance System

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**

---

Isomedix Operations, Inc.  
23 Elizabeth Drive  
Chester  
New York  
10918  
USA

**Gamma Irradiation**

---

Sequel Special Products  
1 Hillside Drive  
Wolcott  
Connecticut  
06716  
USA

**Manufacture**

...making excellence a habit.™

# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 654489**  
 Date: **2019-03-11**  
 Issued To: **Woven Orthopedic Technologies LLC**  
**63 E. Center Street**  
**Suite 3A**  
**Manchester**  
**Connecticut**  
**06040**  
**USA**

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

...making excellence a habit.™

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.