

EC Certificate - Full Quality Assurance System

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

No.**CE 639965**

Issued To:

**Ilion Medical, Inc.
825 Nicollet Mall, Suite 715
Minneapolis
Minnesota
55402
USA**

In respect of:

Design development and manufacture of the sterile NADIA sacro-iliac joint implant system

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):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **24 February 2017**Date: **24 February 2017**Expiry Date: **23 February 2022**

...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.

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 639965**
 Date: **24 February 2017**
 Issued To: **Ilion Medical, Inc.**
825 Nicollet Mall, Suite 715
Minneapolis
Minnesota
55402
USA

Subcontractor:	Service(s) supplied
Bradshaw Medical, Inc. 10325 - 58th Place Kenosha Wisconsin 53144 USA	Manufacture
Isomedix Operations, Inc. North Facility 1880 Industrial Drive Libertyville Illinois 60048 USA	Sterilization
Medin Corporation, Steralon LLC, Medi-Finish LLC 11 Jackson Road Totowa New Jersey 07512 USA	Manufacture

...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 639965**
Date: **24 February 2017**
Issued To: **Ilion Medical, Inc.**
825 Nicollet Mall, Suite 715
Minneapolis
Minnesota
55402
USA

Subcontractor:	Service(s) supplied
Orchid BioCoat 23149 Commerce Drive Farmington Hills Michigan 48335-2723 USA	Packaging
Orchid MPS A division of Orchid Orthopedic Solution, LLC 3233 W. Harvard Street Santa Ana California 92704 USA	Manufacture
Orchid Orthopedic Solutions 331 City Park Drive SE Arab Alabama 35016 USA	Manufacture

...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 639965**
Date: **24 February 2017**
Issued To: **Ilion Medical, Inc.**
825 Nicollet Mall, Suite 715
Minneapolis
Minnesota
55402
USA

Subcontractor:

Service(s) supplied

QNET BV
Kantstraat 19
Haaren
5076 NP
The Netherlands

EU Representative

...making excellence a habit.™

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 639965**
 Date: **24 February 2017**
 Issued To: **Ilion Medical, Inc.**
825 Nicollet Mall, Suite 715
Minneapolis
Minnesota
55402
USA

Date	Reference Number	Action
24 February 2017	8405975	First Issue

...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.