

EC Certificate - Full Quality Assurance System

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

No. CE 622148
Issued To: **BioHorizons Implant Systems, Inc.**
Also Trading as BioHorizons
2300 Riverchase Center
Birmingham
Alabama
35244
USA

In respect of:

Design and manufacture of dental implants, prosthetic devices, surgical instruments for connection to an active device and associated oral reconstruction surgical 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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2015-06-08**

Date: **2019-02-12**

Expiry Date: **2023-06-14**

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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.

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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
Isomedix Operations, Inc. North Facility 1880 Industrial Drive Libertyville Illinois 60048 USA	Gamma Sterilization
Precision One Medical 3923 Oceanic Drive Oceanside California 92056 USA	Manufacture
QTS Packaging 10525 Hampshire Avenue Bloomington Minnesota 55438 USA	Packaging

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Subcontractor:	Service(s) supplied
Quality First International Suites 317 & 318 Burford Business Centre 11 Burford Road London E15 2ST United Kingdom	EU Representative
Sterigenics US, LLC 2015 Spring Road Suite 650 Oak Brook Illinois 60523 USA	Gamma Sterilization

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Certificate History

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Date	Reference Number	Action
08 June 2015	8246277	First Issue – Transfer from another Notified Body
08 June 2018	8937996	Certificate renewal. Change in scope from 'Design and manufacture of dental implants, prosthetic devices, associated surgical instruments for connection to an active device and Autotac titanium tissue Tacs and VIP treatment planning software system' to 'Design and manufacture of dental implants, prosthetic devices, surgical instruments for connection to an active device and associated oral reconstruction surgical devices' Change in clarification of service supplied from machining to manufacture for Significant Subcontractor Precision One Medical
11 September 2018	9634864	Addition of subcontractor Isomedix Operations, Inc.
Current	8406069	Traceable to NB 0086.

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Page 1 of 1

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