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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 sterile dental implants and non-sterile prosthetic devices, surgical instruments for connection to an active device, associated oral reconstruction surgical devices and Intraspin® centrifuges for the preparation of autologous platelet rich fibrin (PRF) for dental, oral and maxillofacial applications.

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

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2015-06-08** Date: **2021-05-18** Expiry Date: **2023-06-14**

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Supplementary Information to CE 622148

Issued To:

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Birmingham
Alabama
35244
USA

Device code	Device name	Intended purpose per IFU
Class IIb		
MD 0403	Dental screw implants	As an artificial root structure for single tooth replacement or fixed bridgework and dental retention
MD 0403	Dental abutments	For restorations of dental implants
MD 0403	AutoTac titanium implants	The fixation of barrier membranes and/or soft tissue used for regeneration of bone and/or soft tissue in the oral cavity
Class IIa		
MD 0401	Dental instruments for use with implant systems	---
MD 1101	Centrifuges for dental, oral and maxillofacial applications	---
MD 1106	AutoTac System handles and instruments	---

First Issued: **2015-06-08** Date: **2021-05-18** Expiry Date: **2023-06-14**

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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 622148**
Date:	**2021-05-18**
Issued To:	**BioHorizons Implant Systems, Inc.** **Also Trading as BioHorizons** **2300 Riverchase Center** **Birmingham** **Alabama** **35244** **USA**

Subcontractor:	**Service(s) supplied**
Altatec GmbH Maybachstraβe 5 71299 Wimsheim Germany	**EU Representative**
Andreas Hettich GmbH & Co. KG Föhrenstraβe 12 78532 Tuttlingen Germany	**Manufacture**
Isomedix Operations, Inc. North Facility 1880 Industrial Drive Libertyville Illinois 60048 USA	**Radiation (Gamma Sterilization)**

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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:

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Date:	**2021-05-18**
Issued To:	**BioHorizons Implant Systems, Inc.** **Also Trading as BioHorizons** **2300 Riverchase Center** **Birmingham** **Alabama** **35244** **USA**

Subcontractor:	**Service(s) supplied**
Precision One Medical 3923 Oceanic Drive Oceanside California 92056 USA	**Manufacture**
QTS Packaging 10525 Hampshire Avenue Bloomington Minnesota 55438 USA	**Packaging**
Quality First International OÜ Laki 30 12915 Tallinn Estonia	**EU Representative**

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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 622148**
Date:	**2021-05-18**
Issued To:	**BioHorizons Implant Systems, Inc.** **Also Trading as BioHorizons** **2300 Riverchase Center** **Birmingham** **Alabama** **35244** **USA**

Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 2015 Spring Road Suite 650 Oak Brook Illinois 60523 USA	**Radiation (Gamma Sterilization)**

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By Royal Charter

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 622148**
Date: **2021-05-18**
Issued To: **BioHorizons Implant Systems, Inc.**
Also Trading as BioHorizons
2300 Riverchase Center
Birmingham
Alabama
35244
USA

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.
12 February 2019	8406069	Traceable to NB 0086.
Current	3331758	Inclusion of 'sterile' for dental implants and 'non-sterile' for the other devices. Extension to scope to include Intraspin® centrifuges. Change of EUAR from Quality First International, UK to Quality First International OÜ, Estonia. Addition of Altatec GmbH as EUAR. Addition of Andreas Hettich GmbH & Co. KG as a significant subcontractor. Update of certificate design to include device table.