By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 773327 R000

Manufacturer: BioHorizons Implant Systems Inc.

Address:
2300 Riverchase Center
Birmingham
Alabama
35244
USA

Single Registration Number: US-MF-000014002

EU Authorised Representative: Altatec GmbH

Address:
Maybachstraße 5
71299 Wimsheim
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2023-09-05**

Current Issue Date: **2024-11-20**

Starting Validity Date: **2024-11-20**

Expiry Date: **2028-09-04**

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Device Schedule: Class III and Class IIb devices

Class IIb, Implantable, Well-established technologies	Intended purpose
Dental Implants	Intended for use in the mandible or maxilla for use as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention.
Dental Abutments and Accessories	Intended for the restoration of dental implants

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Surgical Dental Devices	Class IIa
Centrifuge	Class IIa
Reusable Dental Instruments	Class Ir
For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.	

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2023-09-05	3701904	Issued
2024-07-22	30169536	Supplemented – Addition of device category Centrifuges
Current	30291043	Amended – Addition of a critical subcontractor for Packaging and Control of Sterilization

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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