

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

BioHorizons Implant Systems Inc.
2300 Riverchase Center
Birmingham
Alabama
35244
USA

Facility ID Number: F003304

Holds Certificate No:

MDSAP 704605

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design and manufacturer of dental implants, prosthetic devices, surgical instruments for connection to an active device and associated oral reconstruction surgical devices, and systems for the preparation of autologous platelet rich fibrin (PRF) for dental, oral and maxillofacial applications. Servicing of centrifuges.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-12-02

Effective Date: 2023-10-30

Expiry Date: 2025-10-23



BSI Group America Inc. is an MDSAP recognised auditing organization

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