

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Nobel Biocare AB  
PO Box 5190, 402 26  
Västra Hamngatan 1  
Göteborg  
411 17  
Sweden

Facility ID Number: F000335

Holds Certificate No: **MDSAP 687164**

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

**Brazil:** RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

**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, 21 CFR 821

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-02-12

Effective Date: 2023-10-06

Expiry Date: 2026-10-05



BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 687164**

## Registered Scope:

The design, manufacture and distribution of oral and extra oral prosthetic reconstruction solutions, endosseous implants, abutments, crowns, bridges, dental kits, other associated dental instruments and accessories and software applications for supporting oral, extra-oral and cranio-maxillofacial treatments. The distribution of biomaterials for dental and other surgical applications.



Original Registration Date: 2019-02-12    Effective Date: 2023-10-06

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This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](http://www.bsigroup.com/ClientDirectory). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.